DEPARTMENT OF HEALTH & HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES
CONSORTIUM FOR QUALITY IMPROVEMENT AND SURVEY & CERTIFICATION OPERATIONS
WESTERN DIVISION OF SURVEY AND CERTIFICATION

**SENT BY OVERNIGHT MAIL**

**IMPORTANT NOTICE – PLEASE READ CAREFULLY**

December 7, 2011

Terry Belmont, Chief Executive Officer
University of California Irvine Medical Center
101 City Drive South
Orange, CA 92868

RE: CMS Certification Number (CCN): **05-0348**
(previously Medicare Provider Number)

Dear Mr. Belmont:

Hospitals accredited by the Joint Commission (JC) are "deemed" to meet Medicare Conditions of Participation (COPs) with certain exceptions, not pertinent here. See 42 C.F.R. § 488.4 (a). However, if a complaint validation survey results in a finding that the hospital is out of compliance with one or more of the COPs, the hospital will no longer be deemed to meet any COP. See 42 C.F.R. §488 .7(d).

The California Department of Public Health (CDPH), Orange County District Office, the State Medicare survey agency, reported serious deficiencies from the August 23, 2011 complaint validation survey of University of California Irvine Medical Center, authorized by this office. Specifically, University of California Irvine Medical Center did not comply with the following three (3) Conditions of Participation (COPs):

42 C.F.R. § 482.12 Governing Body
42 C.F.R. § 482.21 QAPI (Quality Assessment and Performance Improvement)
42 C.F.R. § 482.25 Pharmaceutical Services

During this same visit on August 15, 2011, the **CDPH survey team** identified Immediate Jeopardy (IJ) situations in Pharmaceutical Services, 42 C.F.R. § 482.25. **University of California Irvine Medical Center** presented a finalized plan to the survey team on August 16, 2011 and the Immediate Jeopardy situation was abated.

Consequently, effective the date of this letter we are removing your status as a provider deemed to meet Medicare COPs and placing you under the CDPH survey jurisdiction until you demonstrate full compliance. See 42 C.F.R. §488 7(d). This means that the hospital is now subject to all applicable participation and enforcement requirements and may be subject to termination of its Medicare provider agreement.

A description of the deficiencies found by the August 23, 2011 survey is set forth on the enclosed Statement of Deficiencies, Form CMS-2567.

You need to submit evidence documenting actions you have taken to correct these deficiencies. Please submit your evidence of correction to address the survey findings to **this San Francisco Regional office and the CDPH, Orange County District Office, Licensing and Certification,** by close of business, within ten (10) days of receipt of this letter.

The evidence of correction is to be entered on the right side of Form CMS-2567, opposite the deficiency, and must be signed and dated by the administrator or other authorized official.

The evidence of correction of each item must contain the following:

1. How the correction was accomplished, both temporarily and permanently for each individual affected by the deficient practice, including any system changes that must be made.
2. The title of position of the person responsible for correction, e.g. Administrator, Director of Nursing or other responsible supervisory personnel.
3. A description of the monitoring process to prevent recurrences of the deficiency, the frequency of the monitoring and the individual(s) responsible for the monitoring.
4. The date when the immediate correction of the deficiency will be accomplished. Normally this will be no more than thirty (30) days from the date of the exit conference.

If we determine that the submission is timely, credible and otherwise acceptable, we will authorize CDPH to conduct a resurvey. If this survey finds that the hospital meets all applicable Medicare Conditions, deemed status will be restored. See 42 C.F.R. §488.7(e)(3). If we do not receive an acceptable, timely submission, or if a resurvey finds that the hospital is not complying with any COP, we will notify you that we are initiating action to terminate the facility's Medicare provider agreement. See 42 C.F.R. §488.7(d). In the meantime, the removal of deemed status does not limit your ability to bill Medicare, nor does it affect JC accreditation.

Copies of this letter are being sent to the JC, the CDPH-Orange County District Office and Medicaid agency.

If you have any questions, please contact Patricia Jung of my staff at (415) 744-3753.

Sincerely,

Rufus Arther, Manager
Non-LTC Survey, Certification & Enforcement Branch
Western Division of Survey and Certification

Enclosure (50 pages CMS-2567)

cc: The Joint Commission
CDPH – Orange County DO
Title XIX

UNIVERSITY *of* CALIFORNIA, IRVINE • HEALTHCARE

Office of Risk Management
101 The City Drive, Rte. 153
Bldg. 53, Ste. 100
Orange, CA 92868

December 20, 2011

Mr. Rufus Arther, Manager
Non-LTC Survey, Certification & Enforcement Branch
Western Division of Survey and Certification
Department of Health & Human Services
Centers for Medicare & Medicaid Services
90 7th Street, Ste. 5-300(5W)
San Francisco, CA 94103-6707

Subject: CMS Certification Number (CCN): 0S-0348
Evidence of Correction of Cited Deficiencies
Survey Completion Date: August 23, 2011

Dear Mr. Arther:

The attached Form 2S67 reflects credible documentation that all deficiencies cited on the survey ending August 23, 2011 have been corrected and that the University *of* California Irvine Medical Center is now in full compliance with all Medicare Conditions of Participation.

As you review this evidence, please take note of the following significant improvements made to the hospital's Pharmaceutical Services and Patient Safety programs:

1. The implementation of a Pump Safety Committee to oversee all aspects of medication delivery pumps which includes, but is not limited to the assessment of pump technology, the education of health care providers in the use of pumps, the implementation of smart pump safeguards such as medication libraries, and the standardization of work flow, through and including the development of policies governing pump usage.

2. The implementation of an executive-level Patient Safety Steering Committee that is charged with overseeing timely completion of improvement efforts across the organization, prioritizing error reduction activities, and identifying cross-discipline trends and patterns in actual or potential errors.

If you have any questions relative to this Plan of Correction, please contact Nance Hove, Director of Risk & Regulatory Affairs at (714) 4S6-S676.

Sincerely,

Terry A. Belmont
Chief Executive Officer

cc: California Department of Public Health
Licensing & Certification Division
Orange County District Office

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 050348 | A. BUILDING _____ B. WING _____ | C 08/23/2011 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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| UNIVERSITY OF CALIFORNIA IRVINE MED CENTER | 101 CITY DRIVE SOUTH ORANGE, CA 92868 |

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETION DATE |
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| A 000 | INITIAL COMMENTS<br><br>The following reflects the findings of the Department of Public Health during COMPLAINT VALIDATION SURVEY NUMBER CA00278682.<br><br>Representing the Department: Surveyors 21262, HFEN; 22553, HFEN; 22781, HFEN; 25720, HFEN; 17108, Medical Consultant; 27873, Pharmaceutical Consultant; 25052, Pharmaceutical Consultant.<br><br>The survey team entered the hospital at 1015 hours on 8/15/11. The hospital identified their patient census as 285.<br><br>* On 8/15/11 at 1500 hours, the Administrator was notified of Immediate Jeopardy (IJ) to the health and safety of patients receiving medications administered by newly acquired infusion pumps (acquired approximately 3 months ago). There was no hospital-wide training on these pumps. A policy and procedure (P&P) was not developed and approved for the safe use of the pumps. On 7/25/11, MD X overrode a "soft stop" alert (a programming alert informing the programmer the rate and/or dose was high but could be overridden) for Thymoglobulin (an intravenous medication administered during kidney transplants to prevent rejection of the new kidney). There was no "hard stop" alert (a programming alert that would not allow the administration of the medication and could not be overridden) programmed into the infusion pump to prevent life threatening overdoses. Patient 37 received 100 milligrams (mg) of Thymoglobulin over one hour instead of over 6 hours which could have contributed to his death. | A 000 | | |

| LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE |
|---|---|---|
| Terry A Belmont | Chief Executive Officer | 12/20/11 |

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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| A 000 | Continued From page 1<br>* On 7/25/11, the hospital was investigated for a similar safety issue that occurred on 6/15/11. The hospital was unable to ensure that MD K was competent in accurately programming the medication infusion pump for Precedex (a medication used for sedation during procedures). This specific pump did not contain a drug library (the hospital has now removed these type of pumps from all patient care areas except the Neonatal Intensive Care Unit). MD K programmed the pump incorrectly and the 10 year old (Patient 52) received an intravenous dose of Precedex that was over 30 times the prescribed dose. The prescribed dose was 2 micrograms/kilograms/hour (mcg/kg/hr) or 6 micrograms per hour based on Patient 52's body weight. Patient 52 received a dose of 200 mcg within an hour due to the programming error. Patient 52 survived the incident but experienced a drop in heart rate that required two rescue medications (medications used to reverse the drop in heart rate) for his heart rate to stabilize.<br><br>* On 8/16/11 at 1615 hours, the immediate jeopardy was abated when the hospital presented a plan of correction which included the following:<br>A. Pumps must be programmed only by registered nurses who have completed appropriate pump competency with return demonstration.<br>B. Dosage, concentration and flow rates should be chosen from a current drug library (contains medications with dosage and rate limits) that was appropriate for the care area.<br>C. Basic mode (pathway to enter a medication dose and rate when the medication was not in the library) could only be used in rare situations. Verification by another practitioner was to be | A 000 | | |

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| A 000 | Continued From page 2<br>required for any administration by basic mode.<br>D. Soft limits or stops were alerts which indicated that standard dosing had been exceeded. While soft limits might be overridden, this must be done with caution. If a soft limit appeared, the practitioner must re-verify the medication order and pump programming for accuracy.<br>Hard limits or stops were alerts of potentially lethal medication doses that cannot be overridden. The prescriber must be contacted to resolve this discrepancy.<br>E. Independent double check was to be required for initial programming and changes to the programming of intravenous infusion pumps used to deliver opiates, anticoagulants, insulin and chemotherapy.<br>Guidelines:<br>A. Pump safety team should be responsible for oversight of compliance with this policy throughout the hospital. Reports regarding alerts and the frequency of basic mode utilization would be reviewed quarterly and actions would be taken to improve compliance and assure patient safety.<br>Training:<br>Registered nurses training was to occur immediately. No registered nurse would be allowed to program an infusion pump without completing the 8/17/11 education packet.<br>Sign in sheets and staff sheets would be collected to validate completion of training.<br><br>Anesthesiologists, residents, and certified registered nurse anesthetists (CRNAs) were required to use the drug library. If the medication was not in the library, the Anesthesia Patient Officer, in collaboration with the Pharmacy Department, would be contacted and would adjust the libraries accordingly. | A 000 | | |

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| A 000 | Continued From page 3<br>Anesthesia residents or CRNAs must have pump programming verified by their supervising anesthesiologist prior to beginning an infusion. An attending anesthesiologist working independently must have their programming verified by another anesthesiologist.<br>A hard stop alert required contacting an attending anesthesiologist to resolve the discrepancy. If an attending was working independently, the discrepancy must be resolved with another attending anesthesiologist.<br>If basic mode must be used, the pump must be programmed by the attending anesthesiologist (subject to the initial verification process above).<br>Audits should be performed at least quarterly using a tool that was part of the Anesthesia Information Management System.<br><br>Glossary of Abbreviations:<br><br>ADC - Automated Drug Cabinet<br>ASHP - American Association of Health-System Pharmacists<br>BBW - Black Box Warning<br>ED - Emergency Department<br>CMO - Chief Medical Officer<br>CNO - Chief Nursing Officer<br>CQO - Chief Quality Officer<br>CRNA - Certified Registered Nurse Anesthetist<br>DOP - Director of Pharmacy<br>F - Fahrenheit<br>GB - Governing Body<br>HA - Health Affairs<br>H&P - History and Physical<br>IJ - Immediate Jeopardy<br>ICU - Intensive Care Unit | A 000 | | |

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| A 000 | Continued From page 4<br>IOM - Institute of Medicine<br>IV - Intravenous<br>MAR - Medication Administration Record<br>MD - Doctor of Medicine<br>MERP - Medication Error Reduction Program<br>mg/dl - Milligrams per deciliter<br>ml - milliliter<br>MSC - Medication Safety Committee<br>NICU - Neonatal Intensive Care Unit<br>QAPI - Quality Assessment Performance Improvement<br>OR - Operating Room<br>PACU - Post Anesthesia Care Unit<br>PCA - Patient Controlled Analgesia<br>P&P - Policy and Procedure<br>PRN - as needed/necessary<br>RN - Registered Nurse<br>RPH - Registered Pharmacist | A 000 | | |
| A 043 | 482.12 GOVERNING BODY<br><br>The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.<br><br>This CONDITION is not met as evidenced by:<br>Based on interviews, observation and record review, the governing body failed to:<br><br>Findings:<br><br>1. Ensure the Quality Assessment Performance Improvement (QAPI) program was identifying medication errors. Cross reference A266. | A 043 | TAG A043:<br>MEDICATION ERROR REVIEW AND RESOLUTION<br>(Cross reference TAGS A266, A276)<br><br>The enhanced medication error identification process, in place for approximately a year prior to this survey relied on six care area based error identification and review committees reporting to the hospital's Medication Safety Committee. This model has been very effective identifying the systems issues that underlie actual and potential medication errors. This process identified the re-emergence of pump errors and an improvement effort was underway at the time of survey. Since the survey, an executive-level safety oversight committee (Patient Safety Steering Committee) has begun weekly meetings to assure the timely completion of improvement efforts, to prioritize error reduction activities and identify cross-discipline trends and patterns in actual and potential errors. Members of the Committee include the Chief Medical Officer, The Associate Dean for Clinical Operations, the Chief Pharmacy Officer, the Chief Nursing Officer and staff members responsible for error identification and reduction.<br>Monitoring: The Governing Body receives regular monthly reports from the hospital's Quality & Safety Oversight Committee, which in turn, oversees the functioning of the Patient Safety Steering and Medication Safety Committees.<br>Responsible Party: Chief Medical Officer<br>Date of Correction: | 09/18/11 |

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| A 043 | Continued From page 5<br>2. Ensure medication errors were reviewed by the QAPI committee for patient safety. Cross reference A276.<br><br>3. Ensure the QAPI program set priorities for high risk, high volume, problem prone activities related to infusion pump safety. Cross reference A285.<br><br>3. Ensure the QAPI program provided analysis of adverse events related to infusion pumps and implemented preventive/improvement measures for patient safety. Cross reference A288.<br><br>4. Ensure the medical staff enforced its bylaws to ensure the cardiology physicians provided daily progress notes. Cross reference A353.<br><br>5. Ensure safe administration of medications for one of 43 sampled patients (Patient 39). Cross reference A405 #2.<br><br>6. Ensure a safe environment for medication administration. Cross reference A490, A491.<br><br>7. Ensure medical and nursing staff training was sufficient to provide safe drug administration using medication infusion pumps. Cross reference A 398 and A500.<br><br>The cumulative effect of these systemic problems resulted in the hospital's inability to ensure the provision of quality health care in a safe environment. | A 043 | INFUSION PUMP SAFETY (Cross reference TAGS A285, A288, A490)<br>A Pump Safety Committee was created as a sub-committee of the Medication Safety Committee and charged with overseeing and optimizing all aspects of pump use including: the assessment of pump technology; the education of health care providers utilizing pumps; the implementation of smart pump safeguards such as medication libraries, soft stops, hard stops, and alerts; the standardization of workflow through the development and implementation of appropriate policies and procedures; and quality/safety monitoring of pump related processes. The Pump Safety Team reviews all adverse events associated with pumps and identifies specific and system wide changes to enhance safety. Comprehensive medication libraries, including a robust set of hard and soft stops have been developed for Critical Care, Anesthesia, Chemotherapy, Emergency Department, and general medical/surgical settings. A special pump, with an appropriate library, is used for neonatal patients. All libraries are constantly reviewed and revised in response to changes in medication use and reduce the potential for programming errors. Infusion pump libraries have been revised and improved five times since August 2011.<br>Monitoring:<br>A comprehensive set of setting-specific indicators are collected, including the percentage of infusions programmed using the library, the number of hard stops encountered, and the number of soft stops encountered. This data is used by the Pump Safety Team to continuously improve education and perfect pump libraries. The activities of the Pump Safety Team are overseen by the Medication Safety Committee with independent reviews by the Patient Safety Steering Committee.<br><br>Responsible Party: Chief Pharmacy Officer<br>Date of Correction: | 08/11/11 |
| A 263 | 482.21 QAPI<br><br>The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance | A 263 | IMPLEMENTATION OF NEW DEVICES<br>The Quality & Safety Oversight Committee must now approve the implementation of all significant changes in medication delivery devices (such as implementation of new brand or model of infusion pumps). The Committee assures that appropriate policies, procedures and training are in place PRIOR to implementation and established appropriate safety monitoring activities during the implementation process.<br>Monitoring: The activities of the Quality & Safety Oversight Committee are overseen by direct reports to the Governing Body.<br>Responsible Party: Chief Pharmacy Officer<br>Date of Correction: | 08/31/11 |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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| A 263 | Continued From page 6<br>improvement program.<br><br>The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.<br><br>The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.<br><br>This CONDITION is not met as evidenced by:<br>Based on interviews,observation and record review, the hospital failed to implement an effective, ongoing program of quality assessment and performance improvement to improve health outcomes and prevent medical errors.<br><br>Findings:<br><br>1. The QAPI program failed to ensure PCA pump errors that had been persistent since last year were evaluated and acted upon in a manner that quickly addressed and resolved the problems. Cross reference A285.<br><br>2. The QAPI program failed to identify opportunities to improve processes for medication administration via infusion pumps in order to reduce or eliminate recurring errors. Cross reference A276.<br><br>3. The QAPI program failed to ensure that medication infusion pumps that contain drug libraries were appropriately programmed for | A 263 | Prior to the regulatory visit, more than 99% of RNs had completed required Baxter pump training and demonstrated competency. Since 8/17/11, no RN including contract RNs, received a patient assignment prior to completion of Baxter pump training and competency validation.<br><br>Monitoring: Nursing Education monitors training compliance on an ongoing basis.<br><br>Responsible Party: Chief Nursing Officer<br>Completion Date: | 08/17/11 |
| | | | TAG A263<br>MEDICATION ERROR REVIEW AND RESOLUTION:<br><br>The enhanced medication error identification process, in place for approximately a year prior to this survey relied on six care area based error identification and review committees reporting to the hospital's Medication Safety Committee. This model has been very effective identifying the systems issues that underlie actual and potential medication errors. This process identified the re-emergence of pump errors and an improvement effort was underway at the time of survey. Since the survey, an executive-level safety oversight committee (Patient Safety Steering Committee) has begun weekly meetings to assure the timely completion of improvement efforts, to prioritize error reduction activities and identify cross-discipline trends and patterns in actual and potential errors. Members of the Committee include the Chief Medical Officer, The Associate Dean for Clinical Operations, the Chief Pharmacy Officer, the Chief Nursing Officer and staff members responsible for error identification and reduction.<br><br>Monitoring: The Governing Body receives regular monthly reports from the hospital's Quality & Safety Oversight Committee, which in turn, oversees the functioning of the Patient Safety Steering and Medication Safety Committees.<br><br>Responsible Party: Chief Medical Officer<br>Date of Correction: | 09/18/11 |
| | | | INFUSION PUMP SAFETY:<br>A Pump Safety Committee was created as a sub-committee of the Medication Safety Committee and charged with overseeing and optimizing all aspects of pump use including: the assessment of pump technology; the education of health care providers utilizing pumps; the implementation of smart pump safeguards such as medication libraries, soft stops, hard stops, and alerts; the standardization of workflow through the development and implementation of appropriate policies and procedures; and quality/safety monitoring of pump related processes. The Pump Safety Team reviews all adverse events associated with pumps and identifies specific and system | |

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| A 263 | Continued From page 7<br>patient safety. The QAPI program failed to ensure a system was developed to monitor for pump programming compliance throughout the hospital. Cross reference A266, A285.<br><br>4. The QAPI program failed to ensure that appropriate "hard and soft stops" for the medication administration pump libraries were put in place in a prompt manner to provide for patient safety. Cross reference A491.<br><br>5. The QAPI program failed to identify all RNs, including contract nurses, had not been educated regarding the use of medication infusion pumps. Cross reference A500.<br><br>The cumulative effect of these systemic problems resulted in the hospital's inability to ensure the provision of quality health care in a safe environment. | A 263 | wide changes to enhance safety. Comprehensive medication libraries, including a robust set of hard and soft stops have been developed for Critical Care, Anesthesia, Chemotherapy, Emergency Department, and general medical/surgical settings. A special pump, with an appropriate library, is used for neonatal patients. All libraries are constantly reviewed and revised in response to changes in medication use and reduce the potential for programming errors. Infusion pump libraries have been revised and improved five times since August 2011.<br><br>Monitoring:<br>A comprehensive set of setting-specific indicators are collected, including the percentage of infusions programmed using the library, the number of hard stops encountered, and the number of soft stops encountered. This data is used by the Pump Safety Team to continuously improve education and perfect pump libraries. The activities of the Pump Safety Team are overseen by the Medication Safety Committee with independent reviews by the Patient Safety Steering Committee.<br><br>Responsible Party: Chief Pharmacy Officer<br>Date of Correction: | 08/11/11 |
| A 266 | 482.21(a)(1) QAPI MEDICAL ERRORS<br><br>identify and reduce medical errors.<br><br>This STANDARD is not met as evidenced by:<br>Based on interviews and document reviews the hospital failed to ensure the QAPI program had systems in place to identify all potential medication errors. Failing to identify errors could lead to unsafe medication administration and missed opportunities for improvement in patient care. In addition, the hospital failed to identify medication infusion pump errors by failing to understand the process of running discrepancy reports to investigate these errors and evaluating and acting upon them in a manner that quickly addressed and resolved the problems. | A 266 | IMPLEMENTATION OF NEW DEVICES<br>The Quality & Safety Oversight Committee must now approve the implementation of all significant changes in medication delivery devices (such as implementation of new brand or model of infusion pumps). The Committee assures that appropriate policies, procedures and training is in place PRIOR to implementation and established appropriate safety monitoring activities during the implementation process.<br><br>Monitoring: The activities of the Quality & Safety Oversight Committee are overseen by direct reports to the Governing Body.<br><br>Responsible Party: Chief Pharmacy Officer<br>Date of Correction:<br><br>EDUCATION AND COMPETENCY<br>Educational activities related to new policy/process development, including the validation of initial and ongoing competence of appropriate staff members and physicians, is overseen by the Quality and Safety Oversight Committee.<br><br>Monitoring:<br>The activities of the Quality and Oversight Committee are overseen by direct reports to the Governing Body.<br><br>Responsible Party: Chief Executive Officer<br>Date of Correction: | 08/31/11<br><br>08/31/11 |

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| A 266 | Continued From page 8<br>Findings:<br><br>1. On 8/16/11, a medication error report was provided by Pharm I. The report identified that a total of 331 medication errors were reported in the hospital from 2/1/11 to 8/14/11. During an interview with Pharm I and the CNO on 8/18/11 starting at 1250 hours, they stated that an average of 25 medications were administered to each patient each day. They also stated that the hospital averages about 300 patients per day. Thus, 300 patients x 25 doses = 7,500 doses administered each day. Projecting that for 6 months equals 7,500 x 30 days x 6 or 1.35 million doses. So, of approximately 1.35 million doses administered to patients in the hospital between 2/1/11 and 8/14/11, there were 331 errors reported.<br><br>An Emergency Department (ED) transaction report for May 2011 was provided by Pharm I on 8/18/11. The report identified all the medications administered to patients in the ED for May 2011. There were 110 pages in the report each containing 54 rows of administered medications. So, 54 x 110 = 5,940 doses administered in the ED during May 2011. Projected for 6 months that would equal 35,640 doses administered in the ED for 6 months.<br><br>On 8/18/11, a review of the medication error report for the ED from 2/1/11 to 8/14/11 identified that 9 errors were reported by the ED. Out of an estimated 35,000 doses administered in the ED during 6 months, there were 9 reported errors.<br><br>A study entitled "Global Trigger Tool Shows That Adverse Events in Hospitals May be Ten Times | A 266 | All RN's, including contract nurses, are required to complete the Baxter pump computer based training and demonstrate competency via a hands-on return demonstration prior to a patient assignment. Since 8/17/11, no contract RN has received a patient assignment prior to completion of the Baxter pump education and competency validation.<br><br>Monitoring: The Staffing Office monitors contract RN assignments on a daily basis to ensure all appropriate education is completed.<br><br>Responsible Party: Director, Staffing & Placement<br>Completion Date: 08/17/11<br><br>TAG A266: (cross reference TAG A043)<br>MEDICATION ERROR REVIEW AND RESOLUTION:<br><br>The enhanced medication error identification process, in place for approximately a year prior to this survey relied on six care area based error identification and review committees reporting to the hospital's Medication Safety Committee. This model has been very effective identifying the systems issues that underlie actual and potential medication errors. This process identified the re-emergence of pump errors and an improvement effort was underway at the time of survey. Since the survey, an executive-level safety oversight committee (Patient Safety Steering Committee) has begun weekly meetings to assure the timely completion of improvement efforts, to prioritize error reduction activities and identify cross-discipline trends and patterns in actual and potential errors. Members of the Committee include the Chief Medical Officer, The Associate Dean for Clinical Operations, the Chief Pharmacy Officer, the Chief Nursing Officer and staff members responsible for error identification and reduction.<br><br>Monitoring: The Governing Body receives regular monthly reports from the hospital's Quality & Safety Oversight Committee, which in turn, oversees the functioning of the Patient Safety Steering and Medication Safety Committees.<br><br>Responsible Party: Chief Medical Officer<br>Date of Correction: 09/18/11 | |

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| A 266 | Continued From page 9<br>Greater Than Previously Measured" was published in Health Affairs (HA) dated 4/12/11, pages 581 to 589. The study identified that closed medical records for 795 patients from 3 hospitals between, 10/1 and 10/31/04, were reviewed using the Institute for Healthcare Improvment's Global Trigger Tool. The study found that Safety Indicators and Hospital Voluntary Reporting "fail(ed) to detect more than 90 percent of the adverse events that occur among hospitalized patients." The study also showed: a) 38% of identified adverse events were medication errors; b) each patient was subjected to 5.3 medication errors during his/her hospital stay.<br><br>The interview with Pharm I and the CNO described above revealed that there were, on the average, 300 patients in the hospital each day and 7,500 medication doses administered in the hospital each day. Thus 7,500 x 365 equal 2.74 million doses administered per year.<br><br>Using Barker's study of a 10% error rate that would yield 274,000 errors per year. The IOM data would yield 300 errors per day x 365 or about 110,000 errors per year. If a reasonable hospital stay per patient was 10 days, using the more recent HA study would yield a total of (300 divided by 10 times 365) 10,950 errors or almost 17 times the annualized number reported by the hospital in 2011. Even if a very long average stay of 20 days per patient were used, that would yield (300 divided by 20 times 365) 5,475 errors per year. That was still more than 8 times the number reported by the hospital.<br><br>While the error rates from the different studies | A 266 | INFUSION PUMP SAFETY:<br>A Pump Safety Committee was created as a sub-committee of the Medication Safety Committee and charged with overseeing and optimizing all aspects of pump use including: the assessment of pump technology; the education of health care providers utilizing pumps; the implementation of smart pump safeguards such as medication libraries, soft stops, hard stops, and alerts; the standardization of workflow through the development and implementation of appropriate policies and procedures;<br>and quality/safety monitoring of pump related processes. The Pump Safety Team reviews all adverse events associated with pumps and identifies specific and system wide changes to enhance safety. Comprehensive medication libraries, including a robust set of hard and soft stops have been developed for Critical Care, Anesthesia, Chemotherapy, Emergency Department, and general medical/surgical settings. A special pump, with an appropriate library, is used for neonatal patients. All libraries are constantly reviewed and revised in response to changes in medication use and reduce the potential for programming errors. Infusion pump libraries have been revised and improved five times since August<br><br>Monitoring:<br>A comprehensive set of setting-specific indicators are collected, including the percentage of infusions programmed using the library, the number of hard stops encountered, and the number of soft stops encountered. This data is used by the Pump Safety Team to continuously<br>improve education and perfect pump libraries. The activities of the Pump Safety Team are overseen by the Medication Safety Committee with independent<br><br>Responsible Party: Chief Pharmacy Officer<br>Date of Correction:<br><br>IMPLEMENTATION OF NEW DEVICES:<br><br>The Quality & Safety Oversight Committee must now approve the implementation of all significant changes in medication delivery devices (such as implementation of new brand or model of infusion pumps). The Committee assures that appropriate policies, procedures and training is in place PRIOR to implementation and established appropriate safety monitoring activities during the implementation process.<br><br>Monitoring: The activities of the Quality & Safety Oversight Committee are overseen by direct reports to the Governing Body. | 08/11/11 |

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| A 266 | Continued From page 10<br>vary, even the lowest number of errors calculated using the HA study was more than 8 times the number of annualized errors reported by the hospital in 2011. Given the HA study that more than 5,000 errors were likely happening but that only 662 (annualized) errors were identified by the hospital in 2011, there are a potentially significant number of errors occurring in the hospital that are not being reported.<br><br>2. On 8/15/11 at 1104 hours, Pharm I was asked for the policy and procedure (P&P) on how the hospital monitors the safe use of medication infusion pumps, he replied, "We do not have a P&P for this but we will. The Pump Safety Team will be responsible for reviewing the overrides of the pump." Pharm I was asked if the hospital was investigating inappropriate programming overrides and he stated, "We will in the future but the pharmacy department needs to be trained first."<br><br>On 8/15/11, review of Patient 37's medical record revealed the patient was a 63 year old male who had a kidney transplant surgery on 7/25/11. During surgery, an order was given to administer Thymoglobulin 100 mg intravenously to infuse over 6 hours. According to the hospital's incident summary, "A senior anesthesia resident (third year resident) programmed a smart pump that contained a drug library (drug libraries allow for preprogramming dose and rate limits to prevent medication overdose) to deliver the medication over a one hour period instead of the intended six hour period. The pump, which contained the medication in its drug library sent an alert that the "soft limit" (soft stop) was exceeded." The alert was overridden by MD X and the medication was | A 266 | Responsible Party: Chief Pharmacy Officer<br>Date of Correction: | 08/31/11 |

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| A 266 | Continued From page 11<br>administered. There was no programmed "hard stop" (a programming alert that will not allow the administration of the medication and cannot be overridden) entered for this medication in the pump library.<br><br>On 8/15/11 at 1145 hours, Pharm I was asked if there were retrospective audits of the pumps to ensure programming was accurate and "soft stop" overrides were being evaluated. He replied, "Not at this time but we intend to." According to Pharm I, the company who supplied the infusion pumps did not provide adequate training for the hospital to perform the monitoring. He spoke with the company one to two weeks ago and was told they would be out on Thursday 8/18/11 for several days to train the pharmacy staff. | A 266 | | |
| A 276 | 482.21(b)(2)(ii) QAPI IDENTIFY IMPROVEMENT<br><br>[The hospital must use the data collected to--]<br><br>(ii) Identify opportunities for improvement and changes that will lead to improvement.<br><br>This STANDARD is not met as evidenced by:<br>Based on interviews and document reviews the hospital failed to use medication error data collected to identify system weaknesses in order to improve the quality of care.<br><br>Findings:<br><br>1. The Medication Safety Committee (MSC) minutes of 4/28/10 and 8/16/11 were reviewed on 8/15 and 8/16/11 respectively. Appended to each of the minutes were reports entitled "Medication Error Review by MERP 11 Elements." Each of the reports contained the same graphs. | A 276 | TAG A276:<br>MEDICATION ERROR REVIEW AND RESOLUTION:<br>The enhanced medication error identification process, in place for approximately a year prior to this survey relied on six care area based error identification and review committees reporting to the hospital's Medication Safety Committee. This model has been very effective identifying the systems issues that underlie actual and potential medication errors. This process identified the re-emergence of pump errors and an improvement effort was underway at the time of survey. Since the survey, an executive-level safety oversight committee (Patient Safety Steering Committee) has begun weekly meetings to assure the timely completion of improvement efforts, to prioritize error reduction activities and identify cross-discipline trends and patterns in actual and potential errors. Members of the Committee include the Chief Medical Officer, The Associate Dean for Clinical Operations, the Chief Pharmacy Officer, the Chief Nursing Officer and staff members responsible for error identification and reduction.<br><br>Monitoring: The Governing Body receives regular monthly reports from the hospital's Quality & Safety Oversight Committee, which in turn, oversees the functioning of the Patient Safety Steering and Medication Safety Committees.<br><br>Responsible Party: Chief Medical Officer<br>Date of Correction: | 09/18/11 |

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| A 276 | Continued From page 12<br><br>a. The 4/28/10 MSC meeting contained the May 2009 to April 2010 Medication Error Review (MER1) report. There were no minutes for this MSC meeting. The MER1 report read:<br>* Under Prescribing, "Analysis: Number of Prescribing related Medication Events by Month - May 2009 to April 2010." There were no comments under Assessment or Actions.<br>* Under Administration, "Analysis: Number of Administration related Medication Events by Month - May 2009 to April 2010." There were no comments under assessment or actions. There was no evidence of any discussion of medication errors nor any identification of system(s) weaknesses which could provide opportunities for improvement.<br><br>b. The 8/16/11 MSC meeting contained the July 2009 to July 2011 (MER2) report. The MSC minutes read: "Review med error reports, updated trending reports, and determine if further action required." There was no evidence of any discussion of the errors nor any identification of system(s) weaknesses. The MER2 report read:<br>* Under Administration, "Analysis: Number of Administration related Medication Events by Month - July 2009 to July 2011. Assessment: Number of reported errors fairly consistent over the last few months. Several errors associated with failure to administer medication as ordered (i.e. wrong route, VS not monitored, or not given). Five errors associated with pump programming. Actions: To discuss at full MSC. Nursing to address these two areas of concern. There were no reasons identified as to why medications were not administered as ordered. There was no identification of what errors occurred with pump | A 276 | | |

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| A 276 | Continued From page 13<br>programming. There was no evidence of a discussion of why the errors occurred nor any mention of a common thread or theme which caused the errors to occur. There was no evidence of what action(s) needed to be taken to modify existing systems or develop new ones to reduce or eliminate these errors and prevent them from recurring.<br>* Under Dispensing, "Analysis: Number of Dispensing related Medication Events by Month - July 2009 to July 2011. Assessment: Consistent number of events in this category reported in July. Actions: Continue to monitor."<br>There was no evidence of what errors occurred nor why. There was no evidence of any discussion of the trends among the errors nor any action(s) taken to improve processes.<br><br>During a meeting with Pharm I and Pharm II on 8/16/11 starting at 0840 hours, both agreed there was no evidence of any discussion of the commonalities of the errors.<br><br>2. Medication errors from 2/1/11 to 8/14/11, provided by Pharm II and reviewed on 8/16/11, revealed:<br>* There were a total of 331 errors reported.<br>* The four most frequently recurring errors were:<br>a) Wrong Dose - 23%<br>b) Wrong Drug - 19%<br>c) Dose not given (omitted) - 16%<br>d) Wrong Time - 12%<br>The above four error categories comprised 70% of the errors reported during that period. There was no evidence in any of the MSC meeting minutes, reviewed on 8/15 and 8/16/11, that these errors were reported to the committee as the most frequently occurring errors for analysis. | A 276 | | |

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| A 276 | Continued From page 14<br><br>There was no evidence the hospital identified opportunities to improve processes in order to reduce or eliminate recurring medication administration errors. | A 276 | | |
| A 285 | 482.21(c)(1) QAPI PATIENT SAFETY<br><br>The hospital must set priorities for its performance improvement activities that --<br><br>Focus on high-risk, high-volume, or problem-prone areas;<br><br>Consider the incidence, prevalence, and severity of problems in those areas; and<br><br>Affect health outcomes, patient safety, and quality of care.<br><br>This STANDARD is not met as evidenced by:<br>Based on interview and record review, the hospital failed to ensure that medication infusion pumps (these pumps are associated with medication errors that expose patients to a high risk of harm) that contained drug libraries (drug libraries allow for programming dose and rate limits to prevent medication overdose) were appropriately programmed for patient safety and monitored for compliance throughout the hospital. The hospital also failed to ensure PCA pump errors were evaluated and acted upon in a manner that quickly addressed and resolved the problems.<br><br>Findings:<br><br>1. On 8/15/11 at 1104 hours, during an interview Pharm I, the Director of Pharmacy, stated the | A 285 | TAG A285:<br>MEDICATION ERROR REVIEW AND RESOLUTION:<br><br>The enhanced medication error identification process, in place for approximately a year prior to this survey relied on six care area based error identification and review committees reporting to the hospital's Medication Safety Committee. This model has been very effective identifying the systems issues that underlie actual and potential medication errors. This process identified the re-emergence of pump errors and an improvement effort was underway at the time of survey. Since the survey, an executive-level safety oversight committee (Patient Safety Steering Committee) has begun weekly meetings to assure the timely completion of improvement efforts, to prioritize error reduction activities and identify cross-discipline trends and patterns in actual and potential errors. Members of the Committee include the Chief Medical Officer, The Associate Dean for Clinical Operations, the Chief Pharmacy Officer, the Chief Nursing Officer and staff members responsible for error identification and reduction.<br><br>Monitoring: The Governing Body receives regular monthly reports from the hospital's Quality & Safety Oversight Committee, which in turn, oversees the functioning of the Patient Safety Steering and Medication Safety Committees.<br><br>Responsible Party: Chief Medical Officer<br>Date of Correction: | 09/18/11 |

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| A 285 | Continued From page 15<br>hospital was only using medication infusion pumps (except in the neonatal intensive care unit) that contained drug libraries. "We are constantly updating the programming of medications into the library since medication information is dynamic and always changing. We are incorporating 'soft stops' and 'hard stops' if we can. We have hundreds of medications to program and to do this takes time." When asked if all medications that should have "hard stops" had been programmed with these stops Pharm I stated, "We feel we have made good progress but still have ways to go." When Pharm I was asked for the policy and procedure (P&P) on how the hospital monitors the safe use of these pumps, he replied, "We do not have a P&P for this but we will. The Pump Safety Team will be responsible for reviewing the overrides of the pump." Pharm I was asked if the hospital was investigating inappropriate programming overrides and he stated, "We will in the future but the pharmacy department needs to be trained first."<br><br>On 8/15/11, review of Patient 37's medical record revealed the patient was a 63 year old male who had a kidney transplant surgery on 7/25/11. During surgery, an order was given to administer Thymoglobulin 100 mg intravenously to infuse over 6 hours. According to the hospital's incident summary, "A senior anesthesia resident [third year resident] programmed a [Brand Name] smart pump that contains a drug library to deliver the medication over a one hour period instead of the intended six hour period. The pump, which contained the medication in its drug library sent an alert that the "soft limit" [soft stop] was exceeded." The alert was overridden by MD X and the medication was administered. There was | A 285 | INFUSION PUMP SAFETY<br>A Pump Safety Committee was created as a sub-committee of the Medication Safety Committee and charged with overseeing and optimizing all aspects of pump use including: the assessment of pump technology; the education of health care providers utilizing pumps, the implementation of smart pump safeguards such as medication libraries, soft stops, hard stops, and alerts; the standardization of workflow through the development and implementation of appropriate policies and procedures; and quality/safety monitoring of pump related processes. The Pump Safety Team reviews all adverse events associated with pumps and identifies specific and system wide changes to enhance safety. Comprehensive medication libraries, including a robust set of hard and soft stops have been developed for Critical Care, Anesthesia, Chemotherapy, Emergency Department, and general medical/surgical settings. A special pump, with an appropriate library, is used for neonatal patients. All libraries are constantly reviewed and revised in response to changes in medication use and reduce the potential for programming errors. Infusion pump libraries have been revised and improved five times since August 2011.<br><br>Monitoring:<br>A comprehensive set of setting-specific indicators are collected, including the percentage of infusions programmed using the library, the number of hard stops encountered, and the number of soft stops encountered. This data is used by the Pump Safety Team to continuously improve education and perfect pump libraries. The activities of the Pump Safety Team are overseen by the Medication Safety Committee with independent reviews by the Patient Safety Steering Committee.<br><br>Responsible Party: Chief Pharmacy Officer<br>Date of Correction:<br><br>IMPLEMENTATION OF NEW DEVICES<br>The Quality & Safety Oversight Committee must now approve the implementation of all significant changes in medication delivery devices such as implementation of new brand or model of infusion pumps). The Committee assures that appropriate policies, procedures and training is in place PRIOR to implementation and established appropriate safety monitoring activities during the implementation process.<br><br>Monitoring: The activities of the Quality & Safety Oversight Committee are overseen by direct reports to the Governing Body. | 08/11/11 |

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| A 285 | Continued From page 16<br>no programmed "hard stop" entered for this medication.<br><br>On 8/15/11 at 1145 hours, Pharm I was asked if there were retrospective audits of the pumps to ensure programming was accurate and "soft stop" overrides were being evaluated. He replied, "Not at this time but we intend to." According to Pharm I, the company who supplied the infusion pumps did not provide adequate training for the hospital to perform the monitoring. He spoke with the company one to two weeks ago and was told they would be out on Thursday 8/18/11 for several days to train the pharmacy staff. Pharm I stated the Thymoglobulin infusion was labeled appropriately and on the label was printed, "Give over six hours."<br><br>2. On 8/17/11 at 1405 hours, the CNO stated, "We found PCA (Patient Controlled Analgesia) pump errors in 5/11 which had occurred in 4/11." PCA pumps were different than medication infusion pumps, since PCA pumps were utilized by patients to provide pain medication. PCA pumps offered the patients the ability to self administer pain medication on an as needed basis but under a specific dose and schedule to prevent abuse or overdosing. According to the Pump Safety Team minutes, dated 7/14/11, "PCA errors continue to occur despite intensive nurses education. Seven PCA errors were reported over the last few months. Two of these seven errors were reported in the last two weeks."<br><br>According to the Pump Safety Team minutes dated 8/11/11, "PCA errors continue to occur despite intensive nurses education. PCA error reports reflected persistent failures in the | A 285 | Responsible Party: Chief Pharmacy Officer<br>Date of Correction: | 08/31/11 |

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| A 285 | Continued From page 17<br>independent double checks at the time a PCA pump was programmed or reprogrammed. Next meeting to occur in 9/11." There were no documented recommendations made to improve performance in this high risk area. | A 285 | TAG A288:<br>INFUSION PUMP SAFETY<br>A Pump Safety Committee was created as a sub-committee of the Medication Safety Committee and charged with overseeing and optimizing all aspects of pump use including: the assessment of pump technology; the education of health care providers utilizing pumps; the implementation of smart pump safeguards such as medication libraries, soft stops, hard stops, and alerts; the | |
| A 288 | 482.21(c)(2) QAPI FEEDBACK AND LEARNING<br><br>[Performance improvement activities must track medical errors and adverse patient events, analyze their causes and] implement preventive actions and mechanisms that include feedback and learning throughout the hospital.<br><br>This STANDARD is not met as evidenced by:<br>Based on staff interview and record review, the Performance Improvement Committee failed to implement mechanisms that included feedback and learning throughout the hospital to prevent recurrence of potential adverse patient events secondary to the misprogramming of infusion pumps.<br><br>Findings:<br><br>1. On 8/1/11, an adverse patient event was reported by the hospital to the Department. It was reported that on 7/25/11, a medication order to infuse Thymoglobulin 100 mg by intravenous piggy back over 360 minutes to Patient 37 during a kidney transplant surgery. An anesthesiology resident (MD X), over rode the pump's safety alert features and misprogrammed the infusion pump. This resulted in the medication being infused over one hour instead of six hours per instructions on the medication label. The hospital believed there may have been connection between the medication misadministration and the patient's death. | A 288 | standardization of workflow through the development and implementation of appropriate policies and procedures and quality/safety monitoring of pump related processes. The Pump Safety Team reviews all adverse events associated with pumps and identifies specific and system wide changes to enhance safety. Comprehensive medication libraries, including a robust set of hard and soft stops have been developed for Critical Care, Anesthesia, Chemotherapy, Emergency Department, and general medical/surgical settings. A special pump, with an appropriate library, is used for neonatal patients. All libraries are constantly reviewed and revised in response to changes in medication use and reduce the potential for programming errors. Infusion pump libraries have been revised and improved five times since August 2011.<br><br>Monitoring:<br>A comprehensive set of setting-specific indicators are collected, including the percentage of infusions programmed using the library, the number of hard stops encountered, and the number of soft stops encountered. This data is used by the Pump Safety Team to continuously improve education and perfect pump libraries. The activities of the Pump Safety Team are overseen by the Medication Safety Committee with independent reviews by the Patient Safety Steering Committee.<br><br>Responsible Party: Chief Pharmacy Officer<br>Date of Correction:<br><br>MEDICATION ADMINISTRATION<br>Due to time constraints in regulatory reporting requirements, the hospital self-reported the Thymoglobulin mis-administration before it had the opportunity to complete its investigation. The case was internally reviewed by two physicians. In addition, the hospital had the case reviewed by four external physicians, all from non-UC related, highly performing transplant programs at academic medical centers. All six reviews independently opined the mis-administration of Thymoglobulin did not result in either the patient's death or injury to the patient. | 08/11/11 |

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| A 288 | Continued From page 18<br><br>Per the hospital's report, this was the second incident of medication misadministration since May 2011. An incident on 6/15/11 involved a 10-year old who received 30 times the normal sedative medication dose, secondary to misprogramming of an infusion pump.<br><br>On 8/15/11 review of hospital documentation and staff interviews revealed retraining/reeducation of the hospital staff regarding the use of the infusion pumps was limited to the anesthesia department and not throughout the hospital where the infusion pumps were widely being use. There was no P&P in place to serve as guidelines for use of the pumps to prevent any possible future errors. There was no evidence of a system in place to monitor programming of infusion pumps to determine if the hospital's actions were sufficient to correct the programming problems.<br><br>On 8/16/11 at 0800 hours, RN J, charge nurse of the telemetry unit (RN J), stated that none of the nursing staff had been reeducated regarding the use of the hospital's infusion pumps since the incidents described above. RN J further stated, "We're still in the same situation where we could infuse potassium chloride (essential body electrolyte and potentially deadly medication for infusion) or magnesium sulfate (medication for muscle contractions) intravenously, however and at whatever rate we want, by bypassing the basic mode."<br><br>Interviews with other RNs from different nursing floors were conducted. Cross reference A500 a-e. | A 288 | IMPLEMENTATION OF NEW DEVICES<br>The Quality & Safety Oversight Committee must now approve the implementation of all significant changes in medication delivery devices (such as implementation of new brand or model of infusion pumps). The Committee assures that appropriate policies, procedures and training is in place PRIOR to implementation and established appropriate safety monitoring activities during the implementation process.<br><br>Monitoring: The activities of the Quality & Safety Oversight Committee are overseen by direct reports to the Governing Body.<br><br>Responsible Party: Chief Pharmacy Officer<br>Date of Correction: | 08/31/11 |
| | | | On August 16-17, 2011 a clinical update and re-education program was developed and provided to all nurses, including contract nurses, which included medication library guidelines and education on the Pump Safety policy. 100% of assigned staff completed the re-education program prior to receiving a patient assignment.<br><br>Monitoring: The Staffing Office monitors contract RN assignments on a daily basis to ensure all appropriate education is completed. Staff RN competency is validated annually.<br><br>Responsible Party: Chief Nursing Officer<br>Date of Completion | 08/17/11 |
| A 353 | 482.22(c) MEDICAL STAFF BYLAWS | A 353 | | |

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| A 353 | Continued From page 19<br><br>The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:<br><br>This STANDARD is not met as evidenced by:<br>Based on interviews and record review, the hospital failed to ensure the medical staff enforced bylaws to ensure safety for 2 of 43 sampled patients (Patients 37 and 39). This could lead to unsafe medical practice in the hospital.<br><br>Findings:<br><br>According to the closed medical record for Patient 37, he came to the OR (operating room for a kidney transplant on 7/25/11. The medical record revealed that Patient 37 had a pre anesthetic assessment at 0731 hours on 7/25/11 and was taken to the operating room (OR) at 0742 hours. An interview was conducted with MD Z and MD I on 8/18/11 at 0900. An interview with MD X and MD I was conducted at approximately 1000 hours on 8/23/11. MD Z, the physician supervising MD X, stated following induction of anesthesia, she asked MD X if there were any questions regarding the management of Patient 37. MD X told MD Z he was "comfortable" with the case. MD Z stated that she left the OR but returned periodically to review Patient 37 with MD X and to verify that the patient was stable.<br><br>MD X stated he was to initiate an infusion of Thymoglobulin, (a medication used to prevent acute organ rejection). MD X stated that he had used this drug only once before, approximately 6 months earlier at a different location during his training. MD X stated that he would infuse the | A 353 | TAG A353 (cross reference TAG A500)<br>The Supervision policy of the Department of Anesthesia was not followed by MD X, who is a trainee (resident). An investigation was conducted and disciplinary actions were taken against MD X for not following departmental written policies. Re-training for all departmental members, on policies and procedures, was initiated and is taking place regularly and prior to Grand Rounds.<br><br>Monitoring: Is being conducted on an ongoing basis.<br><br>Responsible Party: Chair, Department of Anesthesia<br>Date of Completion: | 08/18/11 |

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| A 353 | Continued From page 20<br>Thymoglobulin over 4 hours, but in programming the infusion pump, he made an error and infused the medication over 1 hour. (By hospital policy, Thymoglobulin must be used only by experienced physicians and infused over a 6 hour interval to prevent acute drug reactions.) MD X denied knowledge of a hospital or pharmacy policy requiring 6 hour infusion of the medication. An entry made by MD X into the anesthesia intraoperative record at 1104 hours to 1204 hours, revealed "Lymphocyte immune globulin, anti thymocyte, IC infusion, 100 mg over 1 hr." When interviewed on 8/23/11, MD X seemed unaware or unwilling to accept the hospital pharmacy directive to infuse the medication over 6 hours.<br><br>The anesthesia record revealed an entry of blood gas results for Patient 37 just prior to 1340 hours. During interview on 8/23/11 MD X recalled obtaining a set of arterial blood gases. The resultant oxygen level was found to be below the normal range and the acid-base balance of Patient 37 was found to be in the acid range. MD X stated that he had "overlooked" the oxygen level of the patient, and took no action to correct the slightly acid level of Patient 37's blood. At 1416 hours, the anesthesia record revealed administration of glycopyrrolate, (an anesthesia reversal agent used to awaken patients from general anesthesia), by MD X. At 1432 hours, MD X proceeded to extubate (remover the breathing tube from the airway) of Patient 37. This was in violation of the Department of Anesthesia rules and regulations that require a trainee physician to page the attending anesthesiologist, in this case, MD Z, to be present during emergence from anesthesia. | A 353 | TAG A353<br>INFUSION PUMP SAFETY<br>A Pump Safety Committee was created as a sub-committee of the Medication Safety Committee and charged with overseeing and optimizing all aspects of pump use including: the assessment of pump technology; the education of health care providers utilizing pumps; the implementation of smart pump safeguards such as medication libraries, soft stops, hard stops, and alerts; the standardization of workflow through the development and implementation of appropriate policies and procedures; and quality/safety monitoring of pump related processes. The Pump Safety Team reviews all adverse events associated with pumps and identifies specific and system wide changes to enhance safety. Comprehensive medication libraries, including a robust set of hard and soft stops have been developed for Critical Care, Anesthesia, Chemotherapy, Emergency Department, and general medical/surgical settings. A special pump, with an appropriate library, is used for neonatal patients. All libraries are constantly reviewed and revised in response to changes in medication use and reduce the potential for programming errors. Infusion pump libraries have been revised and improved five times since August 2011.<br><br>Monitoring:<br>A comprehensive set of setting-specific indicators are collected, including the percentage of infusions programmed using the library, the number of hard stops encountered, and the number of soft stops encountered. This data is used by the Pump Safety Team to continuously improve education and perfect pump libraries. The activities of the Pump Safety Team are overseen by the Medication Safety Committee with independent reviews by the Patient Safety Steering Committee.<br><br>Responsible Party: Chief Pharmacy Officer<br>Date of Correction: | 08/11/11 |

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| A 353 | Continued From page 21<br><br>When interviewed on 8/23/11, MD X stated that he turned away from the patient, following extubation, for a period of possibly 10-30 seconds, to do his electronic charting. MD X stated that he had "forgotten" to page the attending anesthesiologist, MD Z. MD X stated that he was aware of his failure to page MD Z prior to extubating Patient 37, however, he only noted his failure to do so when he turned away from Patient 37 to enter data into the electronic medical record. He then sent a page to MD Z from his computer.<br><br>When interviewed on 8/18/11, MD Z and MD I stated that trainee physicians in anesthesia must not turn away from a patient following extubation, and extubation may not be performed unless a staff anesthesiologist is present. MD Z stated she entered the operating room, having received the page from MD X, to find that Patient 37 had been extubated, had poor color, and was not breathing. MD Z immediately initiated external cardiac compressions and called a "code blue." MD Z instructed MD X to immediately reintubate Patient 37. MD I and MD X both stated that there was a verbal rule in the Department of Anesthesia that an anesthesiologist was not to turn away from a patient following extubation and emergence of the patient from general anesthesia.<br><br>The hospital failed to ensure medical staff bylaws and department of anesthesiology rules had been enforced to provide for safe anesthesia practice for Patient 37.<br><br>2. On 8/17/11, review of the Rules and | A 353 | MD X, in an isolated occurrence, deviated from the department's extubation policy. As indicated previously, disciplinary action was taken against MD X, a resident who did not follow written departmental policy. All departmental residents and faculty (Attending) participated in a re-education of the policy, including that of resident supervision. There is now also a pre-extubation verbal debrief, in which the plan for extubation is discussed between the resident and Attending. This process has been incorporated into the post operative process and is documented as part of the AIMS (Anesthesia Information Management System).<br><br>Monitoring: Is conducted on an ongoing basis<br><br>Responsible Party: Chair, Department of Anesthesia<br>Completion Date: | 08/18/11 |

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| A 353 | Continued From page 22<br>Regulations of the Medical Staff under History and Physical, dated 9/27/10, on page 9; no. 5 stated, "Pertinent progress notes shall be recorded at the time of observation, sufficient to permit continuity of care and transferability. Each entry will show the date and time of each note. Whenever possible each of the patient's clinical problems should be clearly identified in the progress notes and correlated with specific orders as well as results of tests and treatment. Progress notes shall be written at least daily and more often when warranted by the patient's condition."<br><br>In addition, under General Conduct of Care, page 15, no. 11 stated, "If a nurse (RN) has any reason to doubt or question the care provided to any patient or believes that appropriate consultation is needed and has not been obtained, the nurse shall call this to the attention of the nurse's superior who in turn may discuss the matter with the Attending Physician and if the matter is not resolved, she may then refer the matter to the Chief Patient Care Services Officer. If warranted, the Chief Patient Care Services Officer may bring the matter to the attention of the Clinical Department Chief wherein the responsible practitioner has Clinical Privileges."<br><br>On 8/17/11, review of Patient 39's medical record showed the patient had a pacemaker insertion (electrical device to regulate heart beat) on 7/28/11. On 7/29/11, a hematoma (bruise) underneath the pacemaker dressing was documented in the nursing notes. However, there was no evidence the cardiology team examined the surgical site from 7/29/11 to 8/2/11. | A 353 | TAG A353: (Cross reference TAG A043)<br><br>Members of the Cardiology team were re-educated on the requirement to write daily progress notes.<br><br>Monitoring: Random chart audits were conducted for a period of 30 days to ensure daily documentation of care by the Cardiology team was present. 100% compliance was noted.<br><br>Responsible Parties: Chief, Division of Cardiology<br>Chief Administrator, Clinical Services<br>Date of Completion: | 08/30/11 |

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| A 353 | Continued From page 23<br>On 8/18/11 ar 1305 hours, RN K , the nurse who took care of Patient 39 post pacemaker insertion, was interviewed. She stated she was concerned about the huge hematoma. She called the senior cardiology resident. RN K saw the cardiology team in the patient's room, inspecting the pacemaker dressing but there was no progress note written. The Nursing Supervisor of Oncology, who was present during the interview added the attending physician was also notified. Again. the cardiology team did rounds on the patient but there was no progress note written. The Nursing Supervisor of Oncology also added the pacemaker sales representative came to readjust the pacemaker program to better capture the patient's heart beats but she was not sure the cardiology team knew about it or not.<br><br>3. Patient 39's medicine allergy to Ativan, a sedative, was well-documented throughout the medical record and was written on the patient's wristband. On 7/23/11, Patient 39 was given Ativan as the patient was becoming more agitated during a Code Blue situation. Cross reference A405. | A 353 | Cross reference response under TAG A405. | |
| A 397 | 482.23(b)(5) PATIENT CARE ASSIGMENTS<br><br>A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.<br><br>This STANDARD is not met as evidenced by:<br>Based on observations and interviews, the hospital failed to ensure one of three sampled registered nurses (RNs) were competent to calculate medication doses for patients (RN L). | A 397 | TAG A397:<br>SAFE MEDICATION ADMINISTRATION<br><br>Safe medication administration is an expectation of all UC Irvine RN's. The competency for safe medication administration (which includes dosage calculations) is validated during orientation and on an ongoing basis. Ongoing education is conducted based on needs assessment and noted trends.<br><br>Monitoring: Randomized medication pass audits (which include dosage calculations) are conducted proactively to identify any deficits.<br><br>Responsible Party: Chief Nursing Officer<br>Date of Completion: | Ongoing |

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| A 397 | Continued From page 24<br>This could could lead to unsafe patient care.<br><br>Findings:<br><br>During a visit to the Oncology nursing unit on 8/18/11, starting at 0830 hours, staff nurse RN L was asked if she was able to calculate medication doses. RN L said yes. The RNs in the Oncology unit provide care to cancer patients and sometimes must validate the doses of cancer chemotherapy. RN L was given a patient's weight in pounds and a medication dose in milligrams per kilogram. This was sufficient information to calculate the dose for a patient in milligrams. RN L was unable to calculate the dose. This was confirmed by the Oncology nursing supervisor. | A 397 | | |
| A 398 | 482.23(b)(6) SUPERVISION OF CONTRACT STAFF<br><br>Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing services.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the hospital failed to ensure a process was in place to educate and test the competence of one of one sampled registry RN and all registry nurses who worked at the hospital on the use of new infusion pumps (RN1). This did not ensure the pumps would be used correctly and safely by nurses when giving medications and infusions to patients. | A 398 | TAG A398 (cross reference TAG A043)<br>All contract nurses, are required to complete the Baxter pump computer based training and demonstrate competency via a hands-on return demonstration prior to a patient assignment. Since 8/17/11, no contract RN has received a patient assignment prior to completion of the Baxter pump education and competency validation.<br><br>Monitoring: The Staffing Office monitors contract RN assignments on a daily basis to ensure all appropriate education is completed.<br><br>Responsible Parties: Chief Nursing Officer<br>Director, Staffing & Placement<br>Completion Date: | 08/17/11 |

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| A 398 | Continued From page 25<br>Findings:<br><br>On 8/18/11 at 0800 hours, review of hospital personnel files was initiated. Review of the personnel file for RN I showed he was a registry nurse. The file contained a completed test answer sheet. The test was given to determine the nurse's competency to use the new nfusion pumps that were put into use on 6/23/11. The test answer sheet was dated 7/1/11, and had not been scored to show if RN I had passed the test and was qualified to use the pumps.<br><br>All hospital nurses were given a computer based test and classes where the nurses were able to work with the pumps to ensure its proper use and programming. There was no documentation provided to show RN I had taken the pump class to ensure proper use and programming.<br><br>On 8/18/11 at 1100 hours, an interview was done with the Assistant Director of Staff and Patient Placement. RN I's answer sheet was shown to him. The Assistant Director was asked how anyone would know if RN I was qualified to program the new pumps since there was no test score to show if he had passed or failed the test. The Assistant Director then scored the test in front of the surveyors. The score was 80%, the minimum passing score. The Assistant Director added that copies of this test and pump information had been forwarded to all the registry nurses who worked at the hospital. The completed tests were to be sent to his office to be scored prior to being placed in the personnel files. The Assistant Director stated that registry nurses had already used the new pumps in different patient care areas. | A 398 | | |

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| | 050348 | A. BUILDING _____ B. WING _____ | C 08/23/2011 |

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| UNIVERSITY OF CALIFORNIA IRVINE MED CENTER | 101 CITY DRIVE SOUTH ORANGE, CA 92868 |

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| A 398 | Continued From page 26<br><br>The Assistant Director was requested to provide a list of the registry nurses that provide care at the hospital and their tested competency for using the new pumps. This information had not been provided by the time the survey team exited the hospital. | A 398 | | |
| A 404 | 482.23(c) ADMINISTRATION OF DRUGS<br><br>Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice.<br><br>This STANDARD is not met as evidenced by:<br>Based on interview and record review, the hospital failed to ensure that Metronidazole (ME - an antibiotic) was administered as in accordance with California Code of Regulations, Title 22, Section 70263(g)(2) which states medications and treatments shall be administered as ordered.<br><br>Findings:<br><br>During a visit to the Surgical Intensive Care Unit (SICU) on 8/18/11, starting at 0910 hours, the Medication Administration Record (MAR) for Patient 50 was reviewed. Patient 50 was a 12 year old with a preliminary diagnosis of a Clostridium difficile (C diff) infection. According to Lexi-comp, a nationally recognized drug information source, C diff is a bacteria which is toxic and causes diarrhea.<br><br>During an interview with RN P, the patient's nurse, she stated the physician's order for the ME | A 404 | TAG A404:<br>The RN caring for the patient reported that the dosage ordered by the physician differed from the dosage the patient was receiving at home. The medication was held pending clarification/verification of the medication dosage from the physician. The standard of practice is to ensure the dosage is correct prior to administration<br><br>Monitoring: None required<br><br>Responsible Party: Chief Nursing Officer<br><br>Date of Completion: | None Required |

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| A 404 | Continued From page 27<br>was written at 0630 hours (nearly 3 hours before this interview). At 0910 hours the MAR showed that the medication had still not been given. RN P confirmed that she had not yet administered ME to Patient 50. | A 404 | | |
| A 405 | 482.23(c)(1) ADMINISTRATION OF DRUGS<br><br>All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.<br><br>This STANDARD is not met as evidenced by:<br>Based on interviews and record reviews, two of five medical records reviewed regarding the use of patient controlled analgesia (PCA) pumps were not in compliance with approved policies and procedures (Patients 42 and 44). Noncompliance with P&Ps as general guidelines could harm patients. In addition, the hospital failed to ensure one of 43 sampled patients did not receive medications for which an allergy was listed in the medical record. (Patient 39).<br><br>Findings:<br><br>1. At 0950 hours on 8/18/11, during a meeting, the Director of Nursing Research stated that, according to the hospital's P&Ps, the use of PCAs (pumps - used by patients to self administer narcotics within prescribed limits) require a second RN signature to validate the pump was programmed and administered correctly. | A 405 | TAG A405:<br>MEDICATION ERROR REVIEW AND RESOLUTION:<br><br>The enhanced medication error identification process, in place for approximately a year prior to this survey relied on six care area based error identification and review committees reporting to the hospital's Medication Safety Committee. This model has been very effective identifying the systems issues that underlie actual and potential medication errors. This process identified the re-emergence of pump errors and an improvement effort was underway at the time of survey. Since the survey, an executive-level safety oversight committee (Patient Safety Steering Committee) has begun weekly meetings to assure the timely completion of improvement efforts, to prioritize error reduction activities and identify cross-discipline trends and patterns in actual and potential errors. Members of the Committee include the Chief Medical Officer, The Associate Dean for Clinical Operations, the Chief Pharmacy Officer, the Chief Nursing Officer and staff members responsible for error identification and reduction.<br><br>Monitoring: The Governing Body receives regular monthly reports from the hospital's Quality & Safety Oversight Committee, which in turn, oversees the functioning of the Patient Safety Steering and Medication Safety Committees.<br><br>Responsible Party: Chief Medical Officer<br>Date of Correction: 09/18/11<br><br>PUMP DOUBLE CHECK<br>The hospital's Medication Administration policy was revised to streamline workflow and documentation of the independent double check.<br><br>MONITORING: Randomized documentation audits are conducted to validate compliance<br><br>Responsible Party: Chief Nursing Officer<br>Date of Completion: 09/19/11 | |

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| A 405 | Continued From page 28<br>The electronic medical record for Patient 42 was reviewed with Pharm III and the Clinical Nurse Specialist on 8/17/11 starting at 1125 hours. Patient 42 was receiving a narcotic using a PCA in the PACU. The text on the computer screen indicated a second RN had double checked the programming of the PCA. The Clinical Nurse Specialist stated that because of the way the electronic record works in the PACU, a second RN cannot (him or herself) validate the PCA programming in the electronic record. The Clinical Nurse Specialist explained that the primary RN documents the name of the second RN in the computer. The Clinical Nurse Specialist further confirmed there was no documentation in Patient 42's record which identified that a second RN actually validated the programming and administration of the PCA.<br><br>During this same time the electronic medical record for Patient 44 was reviewed. Patient 44 was receiving a narcotic also by a PCA. The PCA was started in the Intensive Care Unit (ICU). The nursing flow sheet was reviewed on the computer screen. (This flow sheet is a hand written document contained in the hard copy medical record and scanned into the electronic record. Thus a hand written signature or initial of the RN can be viewed on the computer screen). The Clinical Nurse Specialist stated there were no initials or signatures on the nursing flow sheet or anywhere else in the patient's record identifying who programmed and administered the PCA pump. This was confirmed by Pharm III.<br><br>2. Per record review on 8/17/11, Patient 39's medicine allergy (Ativan, a sedative medication) | A 405 | INFUSION PUMP SAFETY<br>A Pump Safety Committee was created as a sub-committee of the Medication Safety Committee and charged with overseeing and optimizing all aspects of pump use including: the assessment of pump technology; the education of health care providers utilizing pumps; the implementation of smart pump safeguards such as medication libraries, soft stops, hard stops, and alerts; the standardization of workflow through the development and implementation of appropriate policies and procedures; and quality/safety monitoring of pump related processes. The Pump Safety Team reviews all adverse events associated with pumps and identifies specific and system wide changes to enhance safety. Comprehensive medication libraries, including a robust set of hard and soft stops have been developed for Critical Care, Anesthesia, Chemotherapy, Emergency Department, and general medical/surgical settings. A special pump, with an appropriate library, is used for neonatal patients. All libraries are constantly reviewed and revised in response to changes in medication use and reduce the potential for programming errors. Infusion pump libraries have been revised and improved five times since August 2011.<br><br>Monitoring:<br>A comprehensive set of setting-specific indicators are collected, including the percentage of infusions programmed using the library, the number of hard stops encountered, and the number of soft stops encountered. This data is used by the Pump Safety Team to continuously improve education and perfect pump libraries. The activities of the Pump Safety Team are overseen by the Medication Safety Committee with independent reviews by the Patient Safety Steering Committee.<br><br>Responsible Party: Chief Pharmacy Officer<br>Date of Correction: | 08/11/11 |

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| A 405 | Continued From page 29<br>was well-documented. It was listed on the front of the hard copy medical record, on the admitting H&P, and all the consultation referral reports such as oncology, cardiology, medical intensive care, neurosurgery and palliative care. Per the cardiology consultation note, the allergy to Ativan caused the patient to be hyperactive.<br><br>On 7/23/11, a Code Blue was called for the resuscitation team at 1855 hours when Patient 39 complained to his wife of being very tired and then became unresponsive. The resuscitation lasted approximately 8 minutes. A central intravenous line was placed and a total of 6 mg. of Ativan was administered intravenously (normal dose .5 - 4 mg.). Patient 39 was then transferred to Medical Intensive Care Unit (MICU) at 1925 hours.<br><br>At 1950 hours on 7/23/11, the MICU nurse documented the patient's bilateral pupils were fixed and dilated at 5 mm. Patient 39 was noted to display abnormal posturing which can be a sign of possible brain damage. Per the neurosurgery examination notes on the same day, there were no doll's eyes reaction and no corneal reflexes. There were no reflexes in the upper or lower extremities. Patient 39 did not withdraw or posture to pain. Subsequently, Patient 39 woke up and was able to talk and react.<br><br>On 8/16/11 at 1600 hours, in an interview with Patient 39's wife, the patient previously had Versed (another sedative medication) intravenously while in the hospital and was readily sedated. During the Code Blue, an unidentified resident physician came out of the room who asked her what was Patient 39's reaction when | A 405 | SAFE MEDICATION ADMINSTRATION (cross reference TAGs A043, A353)<br><br>Use of Ativan was concluded to be appropriate in this circumstance. The patient's medical record indicated an allergy to Ativan with a hyperactivity reaction. This was verified hy the patient's wife. As the patient was coding, the physician's clinical judgment was the benefit of Ativan outweighed the risks of hyperactivity. The patient was intubated prior to Ativan administration. The patient oxygenated well and showed no evidence of hyperactivity or agitation.<br><br>Monitoring: The hospital's Medication Safety Committee reviews adverse outcomes associated with code response medications. Trends, if identified, are reported to the hospital's Governing Body.<br><br>Responsible Party: Chief Pharmacy Officer<br>Date of Completion:<br><br>EDUCATION AND COMPETENCY<br>Educational activities related to new policy/process development, including the validation of initial and ongoing competence of appropriate staff members and physicians, is overseen by the Quality and Safety Oversight Committee.<br><br>Monitoring:<br>The activities of the Quality and Safety Oversight Committee are overseen by direct reports to the Governing Body.<br><br>Responsible Party: Chief Executive Officer<br>Date of Correction: | None Required<br><br>08/31/11 |

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| A 405 | Continued From page 30<br>given Ativan. She stated Patient 39 "goes beserk, confused and all over the place." The resident physician then yelled back to the Code Blue team saying, "Go ahead, it is not for respiratory reasons!" Further review of the Medicine team consultation notes showed, the Ativan was given because they felt concerned because he was becoming agitated during the code. | A 405 | | |
| A 450 | 482.24(c)(1) MEDICAL RECORD SERVICES<br><br>All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, interview and record review, the hospital failed to ensure the informed consent form was legible for one of 43 sampled patients (Patient 14). This could result in inaccurate care being delivered.<br><br>Findings:<br><br>On 8/16/11 at 1403 hours, the preoperative area was toured with the Director of Surgical Services. RN H was observed preparing non English speaking Patient 14 for a surgical procedure.<br><br>On 8/16/11 at 1430 hours, the Operation /Procedures consent for Patient 14 read, "Wound exploration left wrist, possible repair nerves/arteries/tendons, possible vein graft vs. autograft from any graft site, possible wound vacuum placement, incision and drainage left wrist, possible nerve (illegible word), possible | A 450 | TAG A450<br>The surveyor reviewed the informed consent document prior to the initiation of the surgical verification process. Multiple checks of correct procedure are done as part of the organization's efforts to eliminate wrong site/side surgery. Most important are the pre-procedure verification and the time-out processes. The pre-procedure verification described in the hospital's Surgical/Procedural Verification policy includes verification of an accurately completed and signed consent document. This allows for the opportunity to clarify any illegible wording in the consent document. For procedures occurring in the main OR, this pre-procedure verification is performed before the patient is moved into the OR and involves the patient or the patient's representative to confirm their understanding of the procedure they are about to undergo. Verification of correct procedure, using the informed consent document, is also repeated as part of the formal pre-procedure time out. This process supports nationally recognized efforts to eliminate wrong site/side surgery and has built-in quality and safety checks.<br><br>Monitoring: The hospital's Patient Safety Steering Committee reviews reports of non-compliance with the hospital's Surgical/Procedural Verification policy to identify potential trends.<br><br>Responsible Party: Chief Medical Officer<br><br>Date of Completion: | None Required |

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| A 450 | Continued From page 31<br>carpal tunnel release." The interpreter who assisted during the interview of the patient revealed the patient did not receive any explanation about the part of the consent where the word was not clearly written.<br><br>On 8/16/11 at 1445 hours, RN F and RN G were interviewed about the unclear word. They both stated it should read as "take;" however, "take" made no sense for any type of surgery. MD A (an orthopedic resident physician) was also interviewed and stated the explanation to the patient was inconsistent based on what was written on the consent.<br><br>The consent's "ilegible word" was later clarified by RN H to be "tube" and not "take." | A 450 | | |
| A 490 | 482.25 PHARMACEUTICAL SERVICES<br><br>The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.<br><br>This CONDITION is not met as evidenced by:<br>Based on interview, medical record, and administrative document review, the hospital failed to ensure that pharmaceutical services carried out its full and complete oversight that met the needs of the patients and prevented significant medication errors.<br><br>Findings: | A 490 | TAG A490:<br>INFUSION PUMP SAFETY<br><br>A Pump Safety Committee was created as a sub-committee of the Medication Safety Committee and charged with overseeing and optimizing all aspects of pump use including: the assessment of pump technology; the education of health care providers utilizing pumps; the implementation of smart pump safeguards such as medication libraries, soft stops, hard stops, and alerts; the standardization of workflow through the development and implementation of appropriate policies and procedures; and quality/safety monitoring of pump related processes. The Pump Safety Team reviews all adverse events associated with pumps and identifies specific and system wide changes to enhance safety. Comprehensive medication libraries, including a robust set of hard and soft stops have been developed for Critical Care, Anesthesia, Chemotherapy, Emergency Department, and general medical/surgical settings. A special pump, with an appropriate library, is used for neonatal patients. All libraries are constantly reviewed and revised in response to changes in medication use and reduce the potential for programming errors. Infusion pump libraries have been revised and improved five times since August 2011. | |

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| A 490 | Continued From page 32<br><br>1. Pharmaceutical services failed to ensure that MD X accurately programmed the medication infusion pump for Thymoglobulin (an intravenous medication administered during kidney transplants to prevent kidney rejection) by following the instructions on the medication label. The hospital failed to ensure that when MD X overrode the "soft stop" alert (a programming alert informing the programmer the rate and/or dose is high but can be overridden) for Thymoglobulin, that a "hard stop" alert (a programming alert that will not allow the administration of the medication and cannot be overridden) was programmed into the infusion pump so life threatening overdoses would not occur. Patient 37 received 100 milligrams (mg) of Thymoglobulin over one hour instead of over 6 hours which could have contributed to his death. Cross reference A500.<br><br>2. Pharmaceutical services failed to ensure the safe and appropriate use of medications and medication devices. Patient 37 received an overdose of a medication, Thymoglobulin as a result of pharmaceutical services failing to program the medication infusion pump with a "hard stop" alert (a programming alert that will not allow the administration of the medication and cannot be overridden). A "hard stop" alert for this medication could have prevented the overdose. Refer to A491.<br><br>* On 8/15/11 at 1500 hours, the Administrator was notified of Immediate Jeopardy (IJ) to the health and safety of patients receiving medications administered by newly acquired infusion pumps (acquired approximately 3 | A 490 | Monitoring:<br>A comprehensive set of setting-specific indicators are collected, including the percentage of infusions programmed using the library, the number of hard stops encountered, and the number of soft stops encountered. This data is used by the Pump Safety Team to continuously improve education and perfect pump libraries. The activities of the Pump Safety Team are overseen by the Medication Safety Committee with independent reviews by the Patient Safety Steering Committee.<br><br>Responsible Party: Chief Pharmacy Officer<br>Date of Correction:<br><br>IMPLEMENTATION OF NEW DEVICES<br>The Quality & Safety Oversight Committee must now approve the implementation of all significant changes in medication delivery devices (such as implementation of new brand or model of infusion pumps). The Committee assures that appropriate policies, procedures and training is in place PRIOR to implementation and established appropriate safety monitoring activities during the implementation process.<br><br>Monitoring: The activities of the Quality & Safety Oversight Committee are overseen by direct reports to the Governing Body.<br><br>Responsible Party: Chief Pharmacy Officer<br>Date of Correction:<br><br>MEDICATION ADMINISTRATION<br>Due to time constraints in regulatory reporting requirements, the hospital self-reported the Thymoglobulin mis-administration before it had the opportunity to complete its investigation. The case was internally reviewed by two physicians. In addition, the hospital had the case reviewed by four external physicians, all from non-UC related, highly performing transplant programs at academic medical centers. All six reviews independently opined the mis-administration of Thymoglobulin did not result in either the patient's death or injury to the patient. | 09/18/11 |

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| A 490 | Continued From page 33<br>months ago). There was no hospital-wide training on these pumps. A policy and procedure (P&P) was not developed and approved for the safe use of the pumps. On 7/25/11, MD X overrode a "soft stop" alert (a programming alert informing the programmer the rate and/or dose was high but could be overridden) for Thymoglobulin (an intravenous medication administered during kidney transplants to prevent rejection of the new kidney). There was no "hard stop" alert (a programming alert that would not allow the administration of the medication and could not be overridden) programmed into the infusion pump to prevent life threatening overdoses. Patient 37 received 100 milligrams (mg) of Thymoglobulin over one hour instead of over 6 hours which could have contributed to his death.<br><br>* On 7/25/11, the hospital was investigated for a similar safety issue that occurred on 6/15/11. The hospital was unable to ensure that MD K was competent in accurately programming the medication infusion pump for Precedex (a medication used for sedation during procedures). This specific pump did not contain a drug library (the hospital has now removed these type of pumps from all patient care areas except the Neonatal Intensive Care Unit). MD K programmed the pump incorrectly and the 10 year old (Patient 52) received an intravenous dose of Precedex that was over 30 times the prescribed dose. The prescribed dose was 2 micrograms/kilograms/hour (mcg/kg/hr) or 6 micrograms per hour based on Patient 52's body weight. Patient 52 received a dose of 200 mcg within an hour due to the programming error. Patient 52 survived the incident but experienced a drop in heart rate that required two rescue | A 490 | | |

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| A 490 | Continued From page 34<br>medications (medications used to reverse the drop in heart rate) for his heart rate to stabilize.<br><br>* On 8/16/11 at 1615 hours, the immediate jeopardy was abated when the hospital presented a plan of correction which included the following:<br>A. Pumps must be programmed only by registered nurses who have completed appropriate pump competency with return demonstration.<br>B. Dosage, concentration and flow rates should be chosen from a current drug library (contains medications with dosage and rate limits) that was appropriate for the care area.<br>C. Basic mode (pathway to enter a medication dose and rate when the medication was not in the library) could only be used in rare situations. Verification by another practitioner was to be required for any administration by basic mode.<br>D. Soft limits or stops were alerts which indicated that standard dosing had been exceeded. While soft limits might be overridden, this must be done with caution. If a soft limit appeared, the practitioner must re-verify the medication order and pump programming for accuracy.<br>Hard limits or stops were alerts of potentially lethal medication doses that cannot be overridden. The prescriber must be contacted to resolve this discrepancy.<br>E. Independent double check was to be required for initial programming and changes to the programming of intravenous infusion pumps used to deliver opiates, anticoagulants, insulin and chemotherapy.<br>Guidelines:<br>A. Pump safety team should be responsible for oversight of compliance with this policy throughout the hospital. Reports regarding alerts | A 490 | | |

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| A 490 | Continued From page 35<br>and the frequency of basic mode utilization would be reviewed quarterly and actions would be taken to improve compliance and assure patient safety.<br>Training:<br>Registered nurses training was to occur immediately. No registered nurse would be allowed to program an infusion pump without completing the 8/17/11 education packet.<br>Sign in sheets and staff sheets would be collected to validate completion of training.<br><br>Anesthesiologists, residents, and certified registered nurse anesthetists (CRNAs) were required to use the drug library. If the medication was not in the library, the Anesthesia Patient Officer, in collaboration with the Pharmacy Department, would be contacted and would adjust the libraries accordingly.<br>Anesthesia residents or CRNAs must have pump programming verified by their supervising anesthesiologist prior to beginning an infusion. An attending anesthesiologist working independently must have their programming verified by another anesthesiologist.<br>A hard stop alert required contacting an attending anesthesiologist to resolve the discrepancy. If an attending was working independently, the discrepancy must be resolved with another attending anesthesiologist.<br>If basic mode must be used, the pump must be programmed by the attending anesthesiologist (subject to the initial verification process above).<br>Audits should be performed at least quarterly using a tool that was part of the Anesthesia Information Management System.<br><br>The cumulative effect of these systemic problems resulted in the hospital's inability to ensure the | A 490 | | |

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| UNIVERSITY OF CALIFORNIA IRVINE MED CENTER | 101 CITY DRIVE SOUTH ORANGE, CA 92868 |

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| A 490 | Continued From page 36<br>provision of quality health care in a safe environment. | A 490 | | |
| A 491 | 482.25(a) PHARMACY ADMINISTRATION<br><br>The pharmacy or drug storage area must be administered in accordance with accepted professional principles.<br><br>This STANDARD is not met as evidenced by:<br>Based on interview and medical record review, the hospital failed to ensure that pharmaceutical services provided safe and appropriate use of medications and medication-devices for three of 43 sampled patients (Patients 37, 39 and 52). Patient 37 received an overdose of a Thymoglobulin as a result of pharmaceutical services failing to program the medication infusion pump with a "hard stop" alert. A "hard stop" alert for this medication could have prevented the overdose. Patient 52 was given an overdose of Precedex as a result of pharmaceutical services not ensuring an anesthesia resident was competent when programming a medication infusion pump. Nursing staff misplaced an applicator for eye medication Patient 39 brought in from home for treatment and prevention of corneal (eye) ulcers.<br><br>Findings:<br><br>1. On 8/15/11, Patient 37's medical record was reviewed. Patient 37 was admitted to the hospital on 7/25/11 for a kidney transplant. An order was given to administer Thymoglobulin 100 mg intravenously, to infusion over 6 hours. According to the hospital's incident summary, "A senior anesthesia resident (third year resident) programmed a smart pump to deliver the | A 491 | TAG A491:<br>INFUSION PUMP SAFETY<br>A Pump Safety Committee was created as a sub-committee of the Medication Safety Committee and charged with overseeing and optimizing all aspects of pump use including: the assessment of pump technology; the education of health care providers utilizing pumps; the implementation of smart pump safeguards such as medication libraries, soft stops, hard stops, and alerts; the standardization of workflow through the development and implementation of appropriate policies and procedures; and quality/safety monitoring of pump related processes. The Pump Safety Team reviews all adverse events associated with pumps and identifies specific and system wide changes to enhance safety. Comprehensive medication libraries, including a robust set of hard and soft stops have been developed for Critical Care, Anesthesia, Chemotherapy, Emergency Department, and general medical/surgical settings. A special pump, with an appropriate library, is used for neonatal patients. All libraries are constantly reviewed and revised in response to changes in medication use and reduce the potential for programming errors. Infusion pump libraries have been revised and improved five times since August 2011.<br><br>Monitoring:<br>A comprehensive set of setting-specific indicators are collected, including the percentage of infusions programmed using the library, the number of hard stops encountered, and the number of soft stops encountered. This data is used by the Pump Safety Team to continuously improve education and perfect pump libraries. The activities of the Pump Safety Team are overseen by the Medication Safety Committee with independent reviews by the Patient Safety Steering Committee.<br><br>Responsible Party: Chief Pharmacy Officer<br>Date of Correction: | 08/11/11 |

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| A 491 | Continued From page 37<br>medication over a one hour period instead of the intended six hour period. The pump, which contained the medication in its drug library sent an alert that the "soft limit " was "exceeded." The pump's alert was overridden by MD X and the medication administered. There was no "hard stop" for this medication programmed in the library to prevent the resident physician from administering the overdose.<br><br>On 8/15/11 at 1104 hours, during an interview, the Director of Pharmacy stated, "There was no 'hard stop' programmed for Thymoglobulin. We are constantly updating the programming of medications into the library. We are incorporating 'soft stops' and 'hard stops' if we can. We have hundreds of medications to program and to do this takes time. We feel we have made good progress but still have a ways to go."<br><br>On 8/17/11 at 0910 hours, MD I, the director of the anesthesiology department, stated there was no " hard stop" programmed in the infusion pump for Thymoglobulin. "If there was a 'hard stop,' the overdose would not occur."<br><br>On 7/25/11, the hospital was investigated for a similar safety issue that occurred on 6/15/11. The hospital was unable to ensure that MD K was competent in accurately programming the medication infusion pump for Precedex (a medication used for sedation during procedures). This specific pump did not contain a drug library (the hospital has now removed these type of pumps from all patient care areas except the Neonatal Intensive Care Unit). MD K programmed the pump incorrectly and 10 year old Patient 52 received an intravenous dose of | A 491 | IMPLEMENTATION OF NEW DEVICES<br>The Quality & Safety Oversight Committee must now approve the implementation of all significant changes in medication delivery devicess (such as implementation of new brand or model of infusion pumps). The Committee assures that appropriate policies, procedures and training is in place PRIOR to implementation and established appropriate safety monitoring activities during the implementation process.<br><br>Monitoring: The activities of the Quality & Safety Oversight Committee are overseen by direct reports to the Governing Body.<br><br>Responsible Party: Chief Pharmacy Officer<br>Date of Correction: | 09/18/11 |

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| A 491 | Continued From page 38<br>Precedex that was over 30 times the prescribed dose. The prescribed dose was 2 micrograms/kilograms/hour (mcg/kg/hr) or 6 micrograms per hour based on Patient 52's body weight. Patient 52 received a dose of 200 mcg within an hour due to the programming error. Patient 52 survived the incident but experienced a drop in heart rate that required two rescue medications (medications used to reverse the drop in heart rate) for his heart rate to stabilize.<br><br>2. Patient 39 was admitted to the hospital on 7/12/11. One of the home medications that was approved by the admitting physician to continue using was an ophthalmic medication that used an applicator to administer the gel into the patient's eyes. The gel medication moistens the eyeballs and prevents further damage to the patient's corneal (eye) ulcer.<br><br>On 8/17/11 at 1600 hours, in an interview with Patient 39's wife, the medication package from home was equipped with an eye applicator. She stated the applicator was needed to hook the gel medication to be able to administer in the eyes. Without the applicator, it would be impossible to administer the eye medication. During Patient 39's admission to the 7th floor Telemetry Unit, the eye applicator was lost and so there was no gel provided to prevent further abrasions of the patient's corneal ulcer.<br><br>On 8/18/11 at 1305 hours, in an interview with RN K who took care of Patient 39, she stated the eye gel applicator was lost for one day. RN K found the eye applicator in between the EKG telemetry screens at the nurses' station. RN K and the Nursing Supervisor of Oncology were unable to | A 491 | This incident was an isolated occurrence and not a systemic occurrence. If a patient is missing part of all of a medication delivery device, the Pharmacy Department will obtain a new device for the patient, or if not feasible, find an available and suitable therapeutic alternative for the patient.<br>Monitoring: Is conducted on an ongoing basis through a review of incident reports to identify trends or systemic issues.<br>Responsible Party: Chief Pharmacy Officer<br>Chief Nursing Officer<br>Date of Completion: | 08/22/11 |

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| A 491 | Continued From page 39<br>explain why the medication applicator was there and not put back with the medication. | A 491 | | |
| A 500 | 482.25(b) DELIVERY OF DRUGS<br><br>In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.<br><br>This STANDARD is not met as evidenced by:<br>Based on interview, medical record and document review, the hospital failed to ensure MD X accurately programmed the medication infusion pump for Thymoglobulin by following the instructions on the medication label. The hospital failed to ensure that when MD X overrode the "soft stop" alert, that a "hard stop" alert was programmed into the infusion pump so life threatening overdoses would not occur. Patient 37 received 100 milligrams (mg) of Thymoglobulin over one hour instead of over 6 hours which could have contributed to his death. The hospital also failed to train their nursing staff throughout the hospital on the use of the infusion pumps. The hospital failed to ensure a policy and procedure that received approval by the appropriate hospital committees was developed and implemented for use of the infusion pumps. This resulted in two of 43 sampled patients receiving overdoses of medications and other patients put at risk of overdose (Patients 37 and 52).<br><br>Findings:<br><br>1. On 8/15/11, Patient 37's medical record was reviewed. Patient 37 was a 63 year old male admitted to the hospital on 7/25/11 for a kidney | A 500 | TAG A500:<br>INFUSION PUMP SAFETY<br>A Pump Safety Committee was created as a sub-committee of the Medication Safety Committee and charged with overseeing and optimizing all aspects of pump use including: the assessment of pump technology; the education of health care providers utilizing pumps; the implementation of smart pump safeguards such as medication libraries, soft stops, hard stops, and alerts; the standardization of workflow through the development and implementation of appropriate policies and procedures; and quality/safety monitoring of pump related processes. The Pump Safety Team reviews all adverse events associated with pumps and identifies specific and system wide changes to enhance safety. Comprehensive medication libraries, including a robust set of hard and soft stops have been developed for Critical Care, Anesthesia, Chemotherapy, Emergency Department, and general medical/surgical settings. A special pump, with an appropriate library, is used for neonatal patients. All libraries are constantly reviewed and revised in response to changes in medication use and reduce the potential for programming errors. Infusion pump libraries have been revised and improved five times since August 2011.<br><br>Monitoring:<br>A comprehensive set of setting-specific indicators are collected, including the percentage of infusions programmed using the library, the number of hard stops encountered, and the number of soft stops encountered. This data is used by the Pump Safety Team to continuously improve education and perfect pump libraries. The activities of the Pump Safety Team are overseen by the Medication Safety Committee with independent reviews by the Patient Safety Steering Committee.<br><br>Responsible Party: Chief Pharmacy Officer<br>Date of Correction: | 08/11/11 |

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| A 500 | Continued From page 40<br>transplant. An order was given to administer Thymoglobulin 100 mg intravenously to infuse over 6 hours. According to the hospital 's incident summary, a senior anesthesia resident programmed a smart pump to deliver the medication over a one hour period instead of the intended six hour period. The pump, which contained the medication in its drug library, sent an alert that the 'soft limit' was exceeded." The alert was overridden by MD X and the medication administered.<br><br>According to the Anesthesia Intraoperative Record, Patient 37 received Thymoglobulin 100 mg. on 7/25/11 at 1104 hours. At 1123 hours, Patient 37 was in normal sinus rhythm (normal heart beat). At 1432 hours, the patient was extubated (breathing tube removed). At 1445 hours, Patient 37 became obtunded (could not be fully aroused), stopped breathing ,and had to be reintubated. At 1448 hours, Patient 37 noted to desaturate (when blood does not have enough oxygen) with a heartrate drop to 32 (normal is above 60). Cardiopulmonary resuscitation (CPR) was started. Patient 37 received epinephrine 1 mg to increase his heart rate. Patient 37 stabilized within a minute and was later transported to the Intensive Care Unit. The patient died shortly before midnight on July 28, 2011.<br><br>On 8/15/11 at 1104 hours, in an interview Pharm 1 (Director of Pharmacy) stated, "The hospital now uses only [brand Name] pumps except in the Neonatal Intensive Care Unit where they use [Brand Name} pumps because these pumps can deliver small doses more accurately. The rest of the hospital switched over to the [1st Brand | A 500 | MEDICATION ADMINISTRATION<br>Due to time constraints in regulatory reporting requirements, the hospital self-reported the Thymoglobulin mis-administration before it had the opportunity to complete its investigation. The case was internally reviewed by two physicians. In addition, the hospital had the case reviewed by four external physicians, all from non-UC related, highly performing transplant programs at academic medical centers. All six reviews independently opined the mis-administration of Thymoglobulin did not result in either the patient's death or injury to the patient. | |

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| A 500 | Continued From page 41<br>Name] pumps about 3 months ago. There has been no policy and procedure developed and approved for the use of these pumps."<br><br>According to California Code of Regulations, Title 22, Section 70263 (c)(1): "The committee (pharmacy and therapeutics committee, or a committee of equivalent composition) shall develop written policies and procedures for establishment of safe and effective systems for procurement, storage, distribution, dispensing and use of drugs and chemicals. The pharmacist in consultation with other appropriate health professionals and administration shall be responsible for the development and implementations of procedures. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate."<br><br>Pharm 1 was asked if there were retrospective audits of the pumps to ensure programming was accurate and "soft stop" overrides were being evaluated. He replied, "Not at this time but we intend to." According to Pharm 1, the pumps' manufacturer did not provide adequate training to hospital pharmacy staff for them to perform the monitoring. He spoke with the manufacturer one to two weeks ago and was told they would be out on Thursday 8/18/11 for several days to train the pharmacy staff. Pham 1 stated the Thymoglobulin infusion was labeled appropriately and specified to infuse over six hours.<br><br>* On 8/17/11 at 0842 hours, during an interview MD X stated, during Patient 37's extubation on 7/25/11 at 1432 hours, MD X did not call the attending anesthesiologist supervising the case | A 500 | IMPLEMENTATION OF NEW DEVICES<br>The Quality & Safety Oversight Committee must now approve the implementation of all significant changes in medication delivery devices (such as implementation of new brand or model of infusion pumps). The Committee assures that appropriate policies, procedures and training is in place PRIOR to implementation and established appropriate safety monitoring activities during the implementation process.<br><br>Monitoring: The activities of the Quality & Safety Oversight Committee are overseen by direct reports to the Governing Body.<br><br>Responsible Party: Chief Pharmacy Officer<br>Date of Correction:<br><br>EDUCATION AND COMPETENCY<br>Educational activities related to new policy/process development, including the validation of initial and ongoing competence of appropriate staff members and physicians, is overseen by the Quality and Safety Oversight Committee.<br><br>Monitoring:<br>The activities of the Quality and Oversight Committee are overseen by direct reports to the Governing Body.<br><br>Responsible Party: Chief Executive Officer<br>Date of Correction: | 09/18/11<br><br>08/31/11 |

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| A 500 | Continued From page 42<br>as is required by the hospital's policy and procedure. " MD X said he forgot to page the faculty."<br>* On 8/17/11 at 0910 hours, MD I, the director of the anesthesiology department, stated there was no "hard stop" programmed in the infusion pump for Thymoglobulin. "If there was a ' hard stop,' the overdose would not occur." He also stated, the anesthesiology department reviewed the case and initiated a root case analysis (RCA). "At this time the RCA is incomplete." A RCA is an investigation of an incident to determine the cause(s) and when resolved restores patient safety.<br>* On 8/18/11 at 0900 hours, during an interview MD Z stated she walked into the operating room after Patient 37 was extubated at 1432 hours, and found him pale and not breathing. She gave the order to MD X to reintubate Patient 37 and ordered epinephrine 1 mg by intravenous push. She also started chest compressions and called a Code Blue (notifying staff this patient is in a medical emergency). "The patient was back in less than a minute and eventually transferred to ICU." On 8/18/11 at 0916 hours, MD I stated, "if MD Z did not come back to the room, Patient 37 would be dead and not four days later."<br>* On 8/23/11 at 1005 hours, during an interview MD X stated he programmed the infusion pump to infuse Thymoglobulin over four hours. When asked why four hours when on the label of the medication it stated to infuse over six hours, he stated he has given it over four hours before. When asked when the last time he administered Thymoglobulin, he stated 12/10. He stated that in 12/10, he didn't program the pump but the attending anesthesiologist programmed the pump and he believes it was given over four hours. | A 500 | | |

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| A 500 | Continued From page 43<br>When asked when he administered the medication the time before that, he stated, "During the first year of my residency." According to Lexicomp on line, a well-known and respected drug information site for healthcare professionals, Thymoglobulin has a black box warning associated with its use. The black box warning states, "Should only be used by physicians experienced in immunosuppressive therapy for the treatment of renal transplant patients." Black box warnings mean that medical studies indicate the medication carries a significant risk of serious or life-threatening adverse events. The black box warning is the strongest warning the FDA (Food and Drug Administration) issues.<br><br>MD X added he found out days later that he programmed the pump to infuse the medication over one hour instead of the four hours he intended. When asked why he did not notify the attending anesthesiologist before extubating Patient 37, he replied that he intended to but didn't send the message. "I would routinely page my attending but my mind was distracted by other things going on personally." After the extubation, MD X turned his back on Patient 1 to document notes in the computer. MD Z walked in the room and found the patient pale and not breathing. When asked if he was concerned about Paient 37 being therapeutic on warfarin (a blood thinning medication) during the procedure, he stated, "The patient was not on warfarin but on aspirin and Plavix." According to the Pre-Anesthesia record signed by MD X, Patient 37 was taking the following anticoagulants prior to admission: Plavix, aspirin, and warfarin.<br><br>On 7/25/11, the hospital was investigated for a | A 500 | The supervision policy of the Department of Anesthesia was not followed by MD X, who is a trainee (resident). An investigation was conducted and disciplinary actions taken against MD X for not following departmental written policies. Re-training for all departmental residents and faculty (Attending) on policies and procedures is conducted on a regular basis, prior to Grand Rounds.<br><br>Monitoring: Ongoing<br><br>Responsible Party: Chair, Department of Anesthesia<br>Date of Correction: | 08/18/11 |

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| A 500 | Continued From page 44<br>similar safety issue that occurred on 6/15/11. The hospital was unable to ensure that MD K was competent in accurately programming the medication infusion pump for Precedex (a medication used for sedation during procedures). This specific pump did not contain a drug library (the hospital has now removed these type of pumps, from all patient care areas except NICU). MD K programmed the pump incorrectly and 10 year old Patient 52 received an intravenous dose of Precedex that was over 30 times the prescribed dose. The prescribed dose was 2 micrograms/kilograms/hour (mcg/kg/hr) or 6 micrograms per hour based on Patient 52's body weight. Patient 52 received a dose of 200 mcg within an hour due to the programming error. Patient 52 survived the incident but experienced a drop in heart rate that required two rescue medications (medications used to reverse the drop in heart rate) for his heart rate to stabilize.<br><br>On 8/15/11 at 1500 hours, the Administrator (CEO) was notified of Immediate Jeopardy (IJ) to the health and safety of patients receiving medications administered by newly acquired nfusion pumps (acquired approximately 3 months ago). There was no hospital wide training on these pumps and policy and procedures were not developed and approved for the safe use of the pumps.<br><br>On 8/16/11 at 1615 hours, the immediate jeopardy was abated when the hospital presented and implemented a thorough plan of correction.<br><br>2. a. RN D was interviewed on 8/17/11 at 0900 hours. The RN stated she was trained in the use of the new infusion puumps a few months ago. | A 500 | Prior to the regulatory visit, more than 99% of RNs had completed required Baxter pump training and demonstrated competency. Since 8/17, no RN, including contract RNs, received a patient assignment prior to completion of Baxter pump training.<br><br>Monitoring: Training is verified before patient assignment for all contract RNs; training is verified by the Nurse Manager during orientation for all new RN hires<br><br>Responsible Party: Chief Nursing Officer<br>Date of Correction: 08/17/11<br><br>EDUCATION AND COMPETENCY<br>Educational activities related to new policy/process development, including the validation of initial and ongoing competence of appropriate staff members and physicians, is overseen by the Quality and Safety Oversight Committee.<br>Monitoring:<br>The activities of the Quality and Oversight Committee are overseen by direct reports to the Governing Body.<br><br>Responsible Party: Chief Executive Officer<br>Date of Correction: 08/31/11 | |

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 050348 | A. BUILDING _____ B. WING _____ | C 08/23/2011 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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| UNIVERSITY OF CALIFORNIA IRVINE MED CENTER | 101 CITY DRIVE SOUTH ORANGE, CA 92868 |

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| A 500 | Continued From page 45<br>The RN stated it was not optimal to use the pump in the basic mode; however, adding oncology drugs to the pump library was a work in progress. When asked if she had received any updated information regarding the use of the pump since the initial training, the RN stated, no she had not.<br><br>b. RN E was interviewed on 8/17/11 at 0905 hours. The RN stated he was trained to be a "super user" of the new infusion pump, meaning he was a resource to the other nursing staff in the use of the pump. The RN stated, when programing the pump he had not encountered a medication that was not in the library. The RN stated if the basic mode had to be used for a non-library drug, the RN stated he would have to program in all the parameters. When asked if this process required a double check with another RN, RN E stated he was unaware if the P&P for the use of the pump required a double check for the basic mode. The RN stated he would have another RN check the programmed dose of a medication if he received a "soft stop" alert. When asked if he had received any updated information regarding the use of the pump since the initial training, the RN stated the only information he had received was the addition of drugs to the pump library.<br><br>c. RN A was interviewed on 8/17/11 at 0930 hours. The RN stated he had been trained in the use of the new infusion pump a few months ago. The RN stated most of the medications he used were in the pump's library; however, the basic mode was available if the medication was not in the library. The RN stated no double check with another RN was required for the use of the basic mode, you just needed to be careful. When asked | A 500 | | |

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| A 500 | Continued From page 46<br>the procedure if a "soft stop" alert was received when programming the pump, the RN stated a double check with another RN was not required. RN E stated, other than notices regarding the additions made to the pump library, he had received no additional information regarding the new infusion pump.<br><br>d. RN B was interviewed on 8/17/11 at 0955 hours. The RN stated medications used on her unit had been added to the library of the the new infusion pump so she had not needed to use the basic mode. When asked the procedure if a "soft stop" alert was received when programming the pump, the RN stated she did not know, she had not encountered an alert. RN B stated she would ask another RN or call on a super user RN for assistance. The RN stated she had not received additional information or training on the pump since the initial training a few months ago.<br><br>e. RN C was interviewed on 8/17/11 at 1015 hours. The RN stated, although she would carefully verify the physician's medication order if she had to use the basic mode to program the new infusion pump, no double check with another RN was required. When asked the procedure if she received a "soft stop" alert during programming, the RN stated she would recheck the order but a double check by another RN was not required. The RN stated she had not received additional information regarding the use of the pump since the initial training. | A 500 | | |
| A1004 | 482.52(b)(2) INPATIENT POST-ANESTHESIA EVALUATION<br><br>[The policies must ensure that the following are provided for each patient:] | A1004 | | |

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| A1004 | Continued From page 47<br><br>An intraoperative anesthesia record.<br><br>This STANDARD is not met as evidenced by:<br>Based on interviews and review of records, the hospital failed to ensure an anesthesia record accurately reflected the sequence of events during adverse reactions or difficulties during anesthesia for one of 43 sampled patients, including the patient's response to treatments (Patient 37). This could lead to unsafe anesthesia practice in the perioperative period.<br><br>Findings:<br><br>On 8/22/11, record review of Patient 37 showed the patient had a kidney transplant surgery on 7/25/11 ending at 1435 hours. A Code Blue (resuscitation of cardiopulmonary arrest) was called at 1445 hours by the scrub technician after the patient's breathing tube was removed by the anesthesiology resident. The rate, rhythm, depth and quality of respiration including the skin color were not described on the narrative report. The pulse oximeter (skin sensor to measure oxygenation), documented as "not reading," was reattached and was recorded at 100%. The anesthesia vital signs graph did not show oxygen desaturation and abnormally slow heart beat though it was documented "patient noted to desaturate shortly after extubation, sinus bradycardia with heart rate of 32."<br><br>The last blood pressure before the resuscitation, per the anesthesia graphic chart, was 80/60 mmHg measured before 1430 hours. This was a decrease from the blood pressure of 110/60 mmHg measured at 1410 hours. A unit of red | A1004 | TAG A1004<br><br>MD X, in an isolated occurrence, deviated from the department's documentation policy. As indicated previously, disciplinary action was taken against MD X, a resident who did not follow written departmental policy. Re-training for all departmental residents and faculty (Attending) on all policies and procedures is conducted on a regular basis prior to Grand Rounds.<br><br>Monitoring: Compliance with departmental policies is monitored on an ongoing basis<br><br>Responsible Party: Chair, Department of Anesthesia<br>Date of Correction: | 08/18/11 |

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| A1004 | Continued From page 48<br>blood cells was infusing at 1421 hours. The infusing Dopamine drip (an intravenous medication that assists in kidney perfusion at low dose [1-5 mcg/min] and a pressor agent to increase heart rate and blood pressure at higher doses), remained unchanged on its rate on the graphic chart despite the reported heart beat at 32 beats per minute and low blood pressure. Per the Code Blue and anesthesia record dated 7/25/11, though the patient had a blood pressure reading and a heart rate, "chest compressions commenced."<br><br>Further review of the anesthesia record showed 2 normal arterial blood gases (ABG-arterial blood test to measure oxygen and carbon dioxide to determine how well lungs are working) at 1130 and 1230 hours. At 1300 hours, the ABG results showed an abnormal oxygen level at 65 (normal is 80-100) with an abnormal blood acid/base balance. Per the anesthesia record, there was no intervention documented to improve the oxygen level or any follow-up test that was done to monitor the blood gas and acid/base balance. Instead, Patient 37 was extubated (breathing tube removed) by MD X at 1432 hours without the presence and approval of MD Z, the attending anesthesiologist.<br><br>On 8/23/11 at 1000 hours, MD X was interviewed. He stated he turned away from Patient 37 for 10-30 seconds after extubation to enter his documentation electronically. He stated he had "overlooked" the oxygen level of the ABG, and took no action to correct the acid level.<br><br>The last set of vital signs were recorded at 1550 hours. The intraoperative summary showed "no | A1004 | | |

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| A1004 | Continued From page 49<br>significant event with no cardiovascular complications." The inaccurate anesthesia record was approved electronically by MD Z, the attending anesthesiologist. | A1004 | | |